

# Exhibit 2

Page 1

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE

\* \* \* \* \*

In Re: Valsartan, Losartan, and Irbesartan  
Products Liability Litigation

\* \* \* \* \*

This Document Relates to:

Roberts, et al., v. Zhejiang Huahai  
Pharmaceutical Co., Ltd., et al.  
Case No: 1:20-cv-00946-RBK-JS

\* \* \* \* \*

REMOTE VIDEOTAPED DEPOSITION OF ANDREW THOMPSON, PhD

May 9, 2025

9:43 a.m. to 3:58 p.m.

REPORTED BY ANITA KORNBURGER  
REGISTERED PROFESSIONAL REPORTER

\* \* \* \* \*

<p style="text-align: right;">Page 2</p> <p>1           A P P E A R A N C E S</p> <p>2   MAZIE SLATER KATZ &amp; FREEMAN, LLC, by</p> <p>3   Mr. Adam M. Slater</p> <p>4   Mr. Christopher Geddis</p> <p>5   103 Eisenhower Parkway, 2nd Floor</p> <p>6   Roseland, NJ 07068</p> <p>7   973-228-9898</p> <p>8   aslater@mazieslater.com</p> <p>9   Appearing by videoconference on behalf of the</p> <p>10   Plaintiffs.</p> <p>11   KIRKLAND ELLIS, by</p> <p>12   Ms. Nina Rose</p> <p>13   1301 Pennsylvania Avenue, N.W.</p> <p>14   Washington, D.C. 20004</p> <p>15   nina.rose@kirkland.com</p> <p>16   Appearing by videoconference on behalf of the</p> <p>17   Defendants.</p> <p>18   GREENBERG TRAURIG, by</p> <p>19   Mr. Steven Harkins</p> <p>20   3333 Piedmont Road NE, Suite 2500</p> <p>21   Atlanta, GA 30305</p> <p>22   harkinss@gtlaw.com</p> <p>23   Appearing by videoconference on behalf of the</p> <p>24   Defendants.</p> <p>25   I N D E X</p> <p>Examination by                      Page</p> <p>Mr. Slater. . . . . 5</p> <p>Ms. Rose. . . . . 167</p> <p>Mr. Slater. . . . . 172</p>	<p style="text-align: right;">Page 4</p> <p>1           TRANSCRIPT OF PROCEEDINGS</p> <p>2           THE VIDEOGRAPHER: Good morning. We are</p> <p>3   now on the record. My name is Phillip Todd. I'm a</p> <p>4   videographer for Golkow, a Veritext division.</p> <p>5           Today's date is May 9, 2025, and</p> <p>6   the time is 9:43 a.m. Eastern.</p> <p>7           This remote video deposition is</p> <p>8   being held in the matter of Valsartan, Losartan,</p> <p>9   and Irbesartan Products Liability Litigation</p> <p>10   related to the case Gaston Roberts, et al., vs</p> <p>11   Zhejiang Huahai Pharmaceutical Company, et al., in</p> <p>12   the United States District Court for the District</p> <p>13   of New Jersey, Camden Vicinage, MDL number 2875.</p> <p>14           The deponent is Dr. Andrew</p> <p>15   Thompson.</p> <p>16           All parties to this deposition are</p> <p>17   appearing remotely and have agreed to the witness</p> <p>18   being sworn in remotely. Due to the nature of</p> <p>19   remote reporting, please pause briefly before</p> <p>20   speaking to ensure all parties are heard</p> <p>21   completely.</p> <p>22           Counsel will be noted on the</p> <p>23   stenographic record.</p> <p>24           The court reporter is Anita</p> <p>25   Kornburger, and will now swear in the witness.</p>
<p style="text-align: right;">Page 3</p> <p>1           E X H I B I T S</p> <p>2                                      Page</p> <p>3   Exhibit No.   Description           Identified</p> <p>4           1    Notice. . . . . 9</p> <p>5           2    Response to notice. . . . . 12</p> <p>6           3    Invoice. . . . . 25</p> <p>7           4    Report. . . . . 40</p> <p>8           5    Warning letter. . . . . 70</p> <p>9           6    E-mail, ZHP00190573. . . . . 112</p> <p>10           7    Most recent CV. . . . . 150</p> <p>11           8    Amended materials reviewed list. . 151</p> <p>12           9    English translation of standard. . 153</p> <p>13   (Original exhibits attached to original transcript.</p> <p>14   Copies provided to all counsel.)</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 5</p> <p>1           ANDREW THOMPSON, MD, called as a</p> <p>2   witness herein, having been first duly sworn on</p> <p>3   oath, was examined and testified as follows:</p> <p>4           E X A M I N A T I O N</p> <p>5   BY MR. SLATER:</p> <p>6   Q. Morning, Dr. Thompson.</p> <p>7   A. Good morning.</p> <p>8   Q. My name's Adam Slater. You understand</p> <p>9   you're here for your deposition?</p> <p>10   A. Do I understand what? I didn't catch</p> <p>11   that.</p> <p>12   Q. Do you understand you're here for your</p> <p>13   deposition?</p> <p>14   A. Yes.</p> <p>15   Q. Have you ever had your deposition taken</p> <p>16   before?</p> <p>17   A. I have.</p> <p>18   Q. How many times?</p> <p>19   A. Two times.</p> <p>20   Q. What were those in connection with?</p> <p>21   A. They were in connection with a patent</p> <p>22   case. There was two different generic companies</p> <p>23   that were trying to break a Merck patent four years</p> <p>24   before the expiration date, and since I was named</p> <p>25   on the patent, I was one of the people that the</p>

<p style="text-align: right;">Page 6</p> <p>1 generics wanted to depose to see what I knew. 2 Q. When were those depositions taken, 3 roughly? 4 A. 2014, about. 5 Q. Were you represented by counsel? 6 A. So Merck had counsel that they hired, and 7 they were my counsel. So I was represented by 8 Merck's counsel. I did not hire separate counsel. 9 Q. Who was that law firm? 10 A. I don't remember. I'd have to look it 11 up. Shawn-something. I don't know. 12 Q. Do you have the transcripts from those 13 depositions? 14 A. No, I do not. 15 Q. Did you ever read them? 16 A. No. 17 Q. They were never provided to you? 18 A. I didn't ask for them. I actually don't 19 remember what the deposition transcripts were. I 20 don't have them, and I don't remember asking for 21 them. 22 Q. You understand you're under oath and must 23 tell the truth in response to all of my questions 24 today? 25 A. Yes.</p>	<p style="text-align: right;">Page 8</p> <p>1 Q. And do you understand that even though 2 this is an informal proceeding over Zoom, that this 3 is of the same force and effect and the same 4 gravity as if you were testifying right now sitting 5 in a federal courtroom in the witness chair in 6 front of a judge and a jury? 7 A. Yes. 8 Q. Did you prepare for this deposition? 9 A. Yes. 10 Q. What did you do to prepare? 11 A. I worked with counsel. 12 Q. Tell me what you did with counsel. 13 A. So we -- they told me the kind of 14 questions I would get and just prepared me, like, 15 emotionally to, you know, to deal with the -- the 16 kind of back and forth that was going to take place 17 in the deposition. 18 Q. For how long did you have that discussion 19 over those subjects? 20 A. I'm going to guess now. Five hours. 21 Q. Did you prepare yourself substantively in 22 terms of preparing by reviewing documents or 23 testimony? 24 A. Yes, I reviewed the documents. 25 Q. Okay. For how long did you review</p>
<p style="text-align: right;">Page 7</p> <p>1 Q. If I ask a question that doesn't make 2 sense to you for any reason, just tell me, okay? 3 A. Okay. 4 Q. The goal here is to get truthful and 5 complete answers to every question. Do you 6 understand that? 7 A. Yes. 8 Q. Therefore, if you can't understand a 9 question or don't feel like you can answer it 10 truthfully and completely, just tell me. Tell me 11 what's unclear, we'll talk about it, and I'll try 12 to ask a question that you feel you can answer 13 truthfully and completely, okay? 14 A. Okay. 15 Q. During the course of the deposition your 16 lawyer or other lawyers potentially may object. 17 That's routine in a deposition. Lawyers object. 18 They're preserving their rights to the future in 19 terms of how this deposition testimony may be used. 20 There's nothing improper about it. 21 Just please allow the objection to be 22 made. And I would assume, in all or almost all 23 cases, you'll be told to go ahead and answer the 24 question, okay? 25 A. Okay.</p>	<p style="text-align: right;">Page 9</p> <p>1 documents to prepare for this deposition? 2 A. So from the very beginning when I started 3 working on the case, or after I wrote my report? 4 Q. Yeah, I'm talking about -- rephrase. I'm 5 asking about the preparation for the deposition 6 itself. We'll talk about the time you spent 7 writing the report separately. 8 A. So I probably spent 30 hours reading 9 reports, rereading reports. You know, I had a 10 question in my mind about what I actually said, so 11 I would go back and look at the report, things like 12 that. 13 Q. Let's mark as Exhibit 1 and put up the 14 deposition notice, please. Actually, let's not put 15 that up as Exhibit 1. Let's put up the defendant's 16 response to the document request contained in the 17 deposition notice. Actually, let me stop again. 18 MR. SLATER: You have the deposition 19 notice, right, Chris? 20 MR. GEDDIS: Yep. 21 MR. SLATER: All right. As Exhibit 1, 22 let's put up the deposition notice. 23 THE WITNESS: This is where I go to the 24 room, that other room? 25 MS. ROSE: Not to the other room. If you</p>

<p style="text-align: right;">Page 10</p> <p>1 go to the link for Golkow remote that you pulled up 2 earlier and it says Dr. Andrew Thompson marked 3 exhibits -- 4 THE WITNESS: Oh, so that's -- so I got 5 the more button. Which button do I press? 6 MR. SLATER: You can see it on the screen 7 as well. 8 MS. ROSE: Here, Dr. Thompson, if you go 9 to your -- either your Outlook or your Chrome, 10 your -- 11 THE WITNESS: Oh, okay. That's where it 12 is. Oh, okay. 13 MS. ROSE: It should say Dr. Andrew 14 Thompson marked exhibits. And you can just hit the 15 refresh button, and then the document file should 16 show up there. 17 THE WITNESS: All right. 18 BY MR. SLATER: 19 Q. Do you see it? 20 A. Should we work off this one that's being 21 shared on the screen? 22 MS. ROSE: Yeah. You can open -- do you 23 see Exhibit 1 now in that folder? 24 THE WITNESS: Veritext. 25 MR. SLATER: What I would suggest is</p>	<p style="text-align: right;">Page 12</p> <p>1 A. Yes. So, I mean, it was pretty much 2 boilerplate stuff like my CV, my invoice, and 3 everything else. I didn't -- there was -- it 4 didn't apply. So I have -- it was very easy for me 5 to get the information that was being requested 6 here. 7 Q. What did you provide to counsel in order 8 to produce to us in response to this deposition 9 notice? 10 A. So first thing, copies of all invoice. I 11 sent -- I sent that to counsel. And then somewhere 12 in here it's asking for my CV. Yeah, the CV. I 13 sent that. And that was all I provided. 14 Q. Let's go now and mark as Exhibit 2 the 15 response to the deposition notice, please. 16 A. Okay. 17 Q. On the screen we have Exhibit 2 titled 18 Defendant's Response to Plaintiff's Document 19 Requests Contained in Notice of Videotaped Oral 20 Deposition of Dr. Andrew Thompson, PhD. Do you see 21 that? 22 A. Yes, I do. 23 Q. Have you seen this document before? 24 A. No, I have not. 25 Q. Let's go to request number one. Request</p>
<p style="text-align: right;">Page 11</p> <p>1 we're going to put it on the screen. If for any 2 reason I ask a question and you feel that you need 3 to look at the whole document, we can either scroll 4 to it or we can look at it if you need to look at 5 it. I'm not going to stop you. I would just say 6 wait to see if you need to depending on my 7 questions. 8 MS. ROSE: I think the doctor would like 9 to look at a document that you're introducing as an 10 exhibit. So I just want to make sure he has access 11 to the folder. 12 THE WITNESS: I do. It worked. I got 13 it. 14 MS. ROSE: Okay. You can open Exhibit 1? 15 THE WITNESS: Yes. 16 MS. ROSE: Okay. 17 THE WITNESS: Yes. 18 BY MR. SLATER: 19 Q. Doctor, you see Exhibit 1 in front of you 20 titled Notice to Take Videotaped Oral Deposition? 21 A. I do. 22 Q. Did you read that deposition notice? 23 A. Yes. 24 Q. Okay. Did you make an effort to provide 25 the responsive information to the requests?</p>	<p style="text-align: right;">Page 13</p> <p>1 number one asked for all invoices for work 2 performed in connection with any consultation or 3 expert work performed for or on behalf of any 4 defendant or their counsel with regard to any 5 issues in this MDL, including but not limited to 6 for the review of documents, review and 7 consultation with regard to plaintiff experts, 8 preparation of Dr. Thompson's report, and 9 preparation for deposition or trial. 10 Do you see that? 11 A. Yes. 12 Q. We were provided one invoice dated May 6, 13 2025. Is that the only responsive invoice that you 14 have? 15 A. Yes. 16 Q. Let's go to request three. 17 A. Okay. 18 Q. This requested copies of any notes, i.e., 19 written or electronic reflecting consulting or 20 litigation work on behalf of any defendant or their 21 counsel with regard to any issues in this MDL that 22 has not been documented in invoices. Do you have 23 any such notes? 24 A. No. 25 Q. Let's go to request four, copies of any</p>

<p style="text-align: right;">Page 14</p> <p>1 notes or other documentation, including PowerPoints 2 for any presentations, seminars or classes given by 3 Dr. Thompson with regard to the chemical formation 4 of nitrosamines under any circumstances, including 5 those formed in ZHP's manufacturing process for 6 valsartan API. 7 Do you have any such documents 8 responsive to that request? 9 A. Okay, so I just want to read -- I get to 10 read the response before I answer? 11 Q. Sure. 12 A. I mean, the answer is no, I don't have 13 anything. 14 Q. You've never given such presentations, 15 seminars or classes? 16 A. That's -- that's correct. 17 Q. Looking at request five, that asked for 18 any notes or other documentation, including 19 PowerPoints or any presentations, seminars or 20 classes given by Dr. Thompson with regard to the 21 technology and methods used for the identification 22 of nitrosamines under any circumstances, including 23 those formed in ZHP's manufacturing process for 24 valsartan API. 25 Have you ever given such -- any such</p>	<p style="text-align: right;">Page 16</p> <p>1 MR. SLATER: Please don't -- no, we're 2 not going to start with speaking objections, Nina. 3 It's an easy question. Come on. Please. 4 BY MR. SLATER: 5 Q. You can answer, Doctor. 6 A. Yeah, so everything I relied upon is in 7 my report. But it says like I relied on the 8 testimony of Najafi and references cited therein. 9 So it's either in my report or it's by -- you know, 10 it's referenced to in the Najafi report which has 11 it in there. So that's what I mean when I say it's 12 all referenced in my report. 13 Q. We'll come back to that. 14 A. Okay. 15 Q. Where are all the documents, articles and 16 everything else that you reviewed as part of your 17 preparation of your report? Where are they 18 actually located? 19 A. They're on a -- they're on a -- on a 20 folder on my computer. 21 MR. SLATER: Counsel, I'm going to ask 22 that that folder be produced in complete form as 23 soon as possible. 24 MS. ROSE: As stated in our objection, 25 and as the witness just stated, he reviewed</p>
<p style="text-align: right;">Page 15</p> <p>1 presentations, seminars, or classes? 2 A. No, I have not. 3 Q. Go to request six: Copies of any 4 documents or articles relied upon for the opinions 5 set forth in the report served. Do you see that? 6 A. Yes. 7 Q. And do you have such documents or 8 articles? 9 A. So everything I relied upon was mentioned 10 in my report, and it was all from existing 11 documentation that Najafi and Hecht that I referred 12 to. 13 Q. If I want to know what you relied on I 14 can read your report and see what you refer to? 15 A. So you're asking me what I relied upon? 16 Q. I'm asking if I want to know -- you just 17 said everything you relied on is mentioned in your 18 report. So I'm just restating that to make sure I 19 understand. 20 If I want to know what documents or 21 articles or materials you specifically relied on in 22 forming your opinions, are they referenced and 23 explicitly described or named in the report? 24 MS. ROSE: Object to the form. I believe 25 Dr. Thompson talked about --</p>	<p style="text-align: right;">Page 17</p> <p>1 documents that were provided by Drs. Hecht and 2 Najafi which are equally available to plaintiffs. 3 MR. SLATER: I get that, but that's not 4 the practice in this litigation. We saw what you 5 wrote to us. We have a right to have everything he 6 relied on to be produced to us so we can actually 7 see what he actually relied on and reviewed as 8 opposed to just telling us it's everything listed. 9 So we have a right to that. It's 10 been produced for every expert in this litigation. 11 It's what was supposed to be done. It's in one 12 folder in his computer. I don't see any reason 13 why, during a break, that can't be provided to us. 14 MS. ROSE: I disagree with that 15 characterization of what's been provided by every 16 expert. We can discuss on a break. I understand 17 your request. No, I understand your request. I'm 18 taking your request under consideration. 19 MR. SLATER: Okay. I'd like to have that 20 resolved at the first break, please. 21 BY MR. SLATER: 22 Q. Looking at request seven, copies of any 23 documents or articles reviewed in connection with 24 the report served, whether listed in the report or 25 attachments thereto.</p>

<p style="text-align: right;">Page 18</p> <p>1 Would all such documents or articles 2 be found in that folder that you told us about 3 that's on your computer? 4 A. "Defendants state that they will provide 5 additional responses as considered by the expert 6 and" -- yeah, all the documents I relied upon would 7 be in that folder, yeah. 8 Q. Look at request ten. We requested any 9 documentation of any research grant the witness has 10 been provided to study any angiotensin two receptor 11 blockers, nitrosamines, or the identification of 12 nitrosamines. Do any such research grants exist? 13 A. No. 14 Q. Have you ever done any study of 15 angiotensin two receptor blockers? 16 A. So I worked on a -- I worked on one at 17 Merck. It was a backup to losartan. 18 Q. What was it called? 19 A. It had an L number. It didn't have -- it 20 didn't have a product name. It wasn't that far in 21 development. And I don't remember the L number. 22 And I don't have any documentation associated with 23 it because when I left Merck, that was all property 24 that belonged to Merck. I couldn't take any of 25 that with me.</p>	<p style="text-align: right;">Page 20</p> <p>1 A. Yeah. We did -- yeah. So we only -- I 2 only worked on it up to the laboratory scale, 3 several kilos, five kilos, and then the project was 4 transferred to somebody else. From there they made 5 larger quantities. But since it was somebody else 6 in a different building, I kind of lost track of 7 it. 8 Q. Were you responsible for the risk 9 assessment of that drug, or was that someone else's 10 responsibility? 11 A. That was somebody else's responsibility. 12 Q. From reviewing the materials and your 13 background, it doesn't appear that you performed 14 risk assessment as part of your work; am I correct? 15 A. Not formally, no. 16 Q. Have you ever done any research into 17 nitrosamines? 18 A. No, I have not. 19 Q. Have you ever done any research into the 20 identification of nitrosamines? 21 A. After 2018, when this issue became a big 22 issue in the pharmaceutical industry, I had to 23 learn about nitrosamines -- this is all on paper, 24 right, not in a lab -- but I had to learn about 25 them, how they form, and methods for their</p>
<p style="text-align: right;">Page 19</p> <p>1 Q. When you say it didn't get far in 2 development, what does that mean? 3 A. I forgot how far it went. Maybe phase 4 two. So it didn't make it to phase three, and it 5 didn't make it to commercial. So only when 6 compounds become commercial and they're approved by 7 the FDA do they get a name like losartan. Before 8 that they will have an L number, L with six digits. 9 And if they get to a certain point, they'll have an 10 MK number with four digits. 11 So the compound I worked on was the L 12 number with six digits after it. And that's as far 13 as the nomenclature got for that particular 14 compound. 15 Q. When you say you worked on that, what was 16 your specific involvement? 17 A. So I was involved in preparing the 18 material. 19 Q. What does that mean? 20 A. So I would -- I would go into a 21 laboratory with -- with reactors, put chemicals 22 into the reactors, and do transformations from A to 23 B to C to D, and come out at the end with a final 24 drug candidate, the API. 25 Q. Would that be at the laboratory scale?</p>	<p style="text-align: right;">Page 21</p> <p>1 detection. I had to become versed in that so I 2 could talk to my customers about it. 3 Q. You were not familiar with those subjects 4 before you learned about the nitrosamines found in 5 the valsartan drugs in 2018? 6 A. That's correct. 7 Q. In your work do you or did you operate 8 gas chromatography? 9 A. Yes. 10 Q. In your work do you or did you operate 11 gas chromatography mass spectrometry machines? 12 A. Yeah, a little bit. But most -- most of 13 that work was done by people that reported to me. 14 I had gotten to the point where I wasn't in the lab 15 anymore, and I was a manager. So I wasn't doing 16 hands-on chemistry. I was watching over people 17 doing it. 18 Q. When did that happen that you became a 19 manager? 20 A. You know, it didn't happen all at once, 21 not like overnight. Gradually I shifted out of the 22 lab. So I probably shifted out by 2025. I wasn't 23 really doing -- I'm sorry, 2005 I wasn't really 24 doing much in the lab after that. 25 Q. Do you know how to operate a GCMS</p>



<p style="text-align: right;">Page 22</p> <p>1 machine?</p> <p>2 A. No. I would have to read instructions on</p> <p>3 how to do it at this point.</p> <p>4 Q. When's the first time in your life you</p> <p>5 ever heard of NDMA?</p> <p>6 A. NDMA?</p> <p>7 Q. Yep.</p> <p>8 A. So I can't recall exactly, but I would</p> <p>9 say it was about -- it was from the valsartan</p> <p>10 recall that I first heard about it. I did not -- I</p> <p>11 don't think I ever heard of that compound's name</p> <p>12 prior to the valsartan recall.</p> <p>13 Q. When did you learn of the existence of</p> <p>14 nitrosamines?</p> <p>15 A. After the valsartan recall.</p> <p>16 Q. Look at request twelve, copies of any</p> <p>17 documents, including protocols or information about</p> <p>18 the chemical formation of nitrosamines under any</p> <p>19 circumstances available to the witness from any</p> <p>20 laboratory or academic institution where he has</p> <p>21 worked, had an appointment, or had access which set</p> <p>22 forth information related to the chemical formation</p> <p>23 of nitrosamines under any circumstances and the</p> <p>24 technology and methods used to identify</p> <p>25 nitrosamines. Do you have any such documents?</p>	<p style="text-align: right;">Page 24</p> <p>1 there's really -- there's really nothing other than</p> <p>2 what analytical technique we would use to detect</p> <p>3 them.</p> <p>4 Q. You said after 2018 with regard to other</p> <p>5 drugs you talked about these things. Who with?</p> <p>6 A. So I had an analytical group. So there</p> <p>7 was a person in charge of the analytical group who</p> <p>8 reported to me. And then she had about 25 people</p> <p>9 under her. And then I had a QA group also, quality</p> <p>10 assurance. I don't think I talked with Mike about</p> <p>11 it.</p> <p>12 But with Leigh we talked about, you</p> <p>13 know, what we were going to do to be able to assay</p> <p>14 for nitrosamines, what was -- what was -- what</p> <p>15 techniques we were going to do, how we were going</p> <p>16 to do this. You know, what was I going to tell</p> <p>17 customers we had in place for it.</p> <p>18 Q. That was not something you had considered</p> <p>19 before that time; correct?</p> <p>20 A. I didn't -- no, I never considered any</p> <p>21 analytical technique to detect nitrosamines prior</p> <p>22 to 2018.</p> <p>23 Q. Did you ever consider the potential</p> <p>24 presence of nitrosamines in any drug before 2018</p> <p>25 when you learned of the valsartan issue?</p>
<p style="text-align: right;">Page 23</p> <p>1 A. I do not.</p> <p>2 Q. Request 14, please. Any communications</p> <p>3 from the witness to any person or entity with</p> <p>4 regard to nitrosamine impurities in any angiotensin</p> <p>5 two receptor blocker or other drug outside of</p> <p>6 communications to counsel who retained the witness.</p> <p>7 Do any such communications exist?</p> <p>8 A. No, they do not.</p> <p>9 Q. So your only communications with anybody</p> <p>10 in the world about nitrosamine impurities as</p> <p>11 described in that request would be in the context</p> <p>12 of your communications with counsel; correct?</p> <p>13 MS. ROSE: Object to the form. Misstates</p> <p>14 the witness.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. Is that true?</p> <p>17 A. Yeah. So any nitrosamine impurities in</p> <p>18 an A2 receptor blocker, yeah, so the only people I</p> <p>19 discussed that with is counsel.</p> <p>20 Q. This also says any other drug. That</p> <p>21 would be true of any drug; correct?</p> <p>22 A. Yeah, any -- so any -- I mean, we talked</p> <p>23 about -- after 2018 we talked about these things,</p> <p>24 but there was no written communications. I</p> <p>25 wouldn't have access to those e-mails now. And</p>	<p style="text-align: right;">Page 25</p> <p>1 A. No.</p> <p>2 Q. Okay. We can put that document down and</p> <p>3 we can go to Exhibit 3, which is the invoice.</p> <p>4 A. Okay.</p> <p>5 Q. We marked as Exhibit 3 a document that</p> <p>6 says at the top confidential. It's dated May 6,</p> <p>7 2025. It says, "The following table shows the days</p> <p>8 and hours utilized for the valsartan project in</p> <p>9 March and April 2025." Do you see that?</p> <p>10 A. Yes, I do.</p> <p>11 Q. Is this an accurate listing of what you</p> <p>12 did on each of those days for those amounts of</p> <p>13 time?</p> <p>14 A. Yes, it is.</p> <p>15 Q. Did you have a chance to review this and</p> <p>16 make sure it was absolutely correct before today?</p> <p>17 A. Well, I put this thing together, so I</p> <p>18 didn't have to really review it. But I did have a</p> <p>19 chance. But I'm the one who put this together, so</p> <p>20 I didn't have to review it.</p> <p>21 Q. How were you first contacted to become</p> <p>22 involved in this litigation?</p> <p>23 A. So I received a phone call from -- I</p> <p>24 assume he's an attorney -- Paul, asking me, you</p> <p>25 know, if I wanted to consult on a certain issue,</p>



<p style="text-align: right;">Page 26</p> <p>1 and I think feeling out my capabilities to decide 2 if I was an adequate fit for the law firm and if I 3 was interested. 4 So I received that call probably 5 before March 22nd, or maybe that was the first call 6 we set up a Zoom call. I can't remember exactly 7 how it started. But I received a call from Paul. 8 And he -- 9 Q. Okay. And that would have taken on or 10 about March 22, 2025? 11 A. Yes. 12 Q. Do you know Paul's last name? 13 A. Kolter. I don't remember exactly. 14 Kolter. 15 Q. Do you know what law firm he works at? 16 A. Kirkland. 17 Q. Have you ever been retained to consult or 18 act as an expert witness in any litigation before 19 this one? 20 A. No. I mean, just -- just the Merck -- 21 just that Merck patent situation. But... 22 Q. That one you had personal involvement 23 with 'cause you were on the patent; right? 24 A. Right. 25 Q. So other than this litigation where</p>	<p style="text-align: right;">Page 28</p> <p>1 project. 2 Q. Do you know anybody that, to your 3 knowledge, has been or is affiliated or works with 4 ZHP? 5 A. No. 6 Q. How about their United States entities, 7 Solco, Princeton, or Huahai US? 8 A. No, I do not. 9 Q. Had you ever heard of ZHP before you were 10 contacted on this case? 11 A. No. 12 Q. Have you spoken to anybody at ZHP, Solco, 13 Princeton, or Huahai US? 14 A. No. 15 Q. As part of the work that you did in this 16 case, did you request any documents from counsel, 17 or did you just review what was provided to you? 18 A. I reviewed what was provided. 19 Q. Did you do any independent research? 20 A. No, there was -- the documents that were 21 included in the witness testimony were adequate for 22 me to make my decision to have an opinion. 23 MR. SLATER: Move to strike after no. 24 MS. ROSE: Object. Adam, we've been 25 getting strong, strong objections that moving to</p>
<p style="text-align: right;">Page 27</p> <p>1 you've been asked to be an expert witness, have you 2 ever consulted or been an expert in any other 3 litigation where you didn't have personal 4 involvement? 5 A. No. 6 Q. Do you know how Paul found you, why he 7 identified you as a potential witness in this case? 8 A. Yes, I do. 9 Q. How did that happen? 10 A. This is from what Paul told me, but he 11 had called a friend of mine who's a professor at 12 Vanderbilt -- and I don't know what they 13 discussed -- but that friend of mine recommended me 14 to -- recommended Paul call me. 15 Q. Who's that professor at Vanderbilt? 16 What's his name? 17 A. Gary Sarnakowski (phonetic.) 18 Q. How do you know him? 19 A. I know him from graduate school. 20 Q. Are you friends? 21 A. Yes, we are. 22 Q. Did you ever work with him? 23 A. No. I mean, he worked in the same group 24 that I was in at Penn, but we never -- I never 25 worked for him, no, or with him on the same</p>	<p style="text-align: right;">Page 29</p> <p>1 strike is -- 2 MR. SLATER: Oh, you're right, Nina. You 3 know what? I forgot. Thank you for calling me. I 4 was -- I've been doing state court litigation again 5 and -- where you do move to strike. So I agree. 6 I'll withdraw the motion to strike because our 7 ability to move to strike testimony is preserved 8 without having to say it. Sorry, I forgot. Thank 9 you for reminding me. 10 MS. ROSE: No problem. 11 MR. SLATER: It's hard to teach an old 12 dog new tricks. 13 THE WITNESS: Tell me about it. 14 BY MR. SLATER: 15 Q. Did you do any independent literature 16 search as part of your work in this case? 17 A. No. 18 Q. From reading your report -- which we'll 19 come back to -- I'll rephrase. 20 From reading your report, it appears 21 that your expertise is in the field of organic 22 chemistry; is that correct? 23 A. Organic synthesis, yes. 24 Q. Let me rephrase it then. In terms of 25 what you're holding yourself out as an expert in</p>

<p style="text-align: right;">Page 30</p> <p>1 this case on, is it organic synthesis?</p> <p>2 A. Yes.</p> <p>3 Q. What does organic synthesis mean?</p> <p>4 A. It's preparing -- synthesizing new</p> <p>5 molecules from existing building blocks. So it's</p> <p>6 the actual steps you take to make a chemical bond</p> <p>7 to change one molecule into another one.</p> <p>8 Q. If I understand that correctly, you're</p> <p>9 talking about the actual development in the</p> <p>10 laboratory of the drug substance?</p> <p>11 A. It's the synthesis -- it's the</p> <p>12 development of the synthesis of the drug substance.</p> <p>13 Q. When you say the development of the</p> <p>14 synthesis, just tell me more specifically what that</p> <p>15 means. When you refer to the synthesis, is that</p> <p>16 the actual method to manufacture that drug product?</p> <p>17 A. Yes, drug substance.</p> <p>18 Q. Is that the intent, that that drug</p> <p>19 substance would ultimately be developed into an</p> <p>20 API?</p> <p>21 A. Yeah, the drug -- the synthesis that</p> <p>22 we're working on, the last step of the synthesis is</p> <p>23 the API, prepares the API.</p> <p>24 Q. And that's all at the lab scale; correct?</p> <p>25 A. At kilo lab scale.</p>	<p style="text-align: right;">Page 32</p> <p>1 particular time during this process, or is it just</p> <p>2 more generic that you know you were reviewing</p> <p>3 documents?</p> <p>4 MS. ROSE: Object to the form.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. Do you get what I'm saying? I'm asking</p> <p>7 if you were able to say on this day it says</p> <p>8 document review, but I know on that day I was</p> <p>9 reviewing these documents.</p> <p>10 MS. ROSE: Object to form.</p> <p>11 THE WITNESS: No, I can't -- I can't say</p> <p>12 that.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. When it refers to report preparation,</p> <p>15 what does that mean?</p> <p>16 A. The witness report that was -- was</p> <p>17 provided. So there's reading documents, forming an</p> <p>18 opinion, and then actually writing the report.</p> <p>19 Q. Just to come back to one thing we were</p> <p>20 talking about a moment ago. You said that your</p> <p>21 expertise that you bring to this case is in the</p> <p>22 field of organic synthesis; correct?</p> <p>23 A. Yes.</p> <p>24 MS. ROSE: Object to the form.</p> <p>25 THE WITNESS: Sorry.</p>
<p style="text-align: right;">Page 31</p> <p>1 Q. Is kilo lab scale otherwise known as</p> <p>2 pilot scale?</p> <p>3 A. It's just before. So pilot scale I</p> <p>4 consider to be 50 kilos, hundred kilos. And kilo</p> <p>5 lab is five to ten kilos. And they supply</p> <p>6 different phases of development.</p> <p>7 Q. So your development work has been at the</p> <p>8 laboratory level up to five to ten kilos of</p> <p>9 product?</p> <p>10 A. Yeah. We prepare product for phase one</p> <p>11 clinical trials. Substance, I'm sorry.</p> <p>12 Q. If I understand correctly, your</p> <p>13 development work would be at the lab scale up to</p> <p>14 five to ten kilograms. And then if development</p> <p>15 process were to continue after that, it would then</p> <p>16 go to pilot scale, and that would be another --</p> <p>17 those would be other people that would conduct the</p> <p>18 pilot scale?</p> <p>19 A. Yes, as is typical in the industry.</p> <p>20 That's the way it's done.</p> <p>21 Q. When I look at the description in your</p> <p>22 invoice of what you did, it refers to Zoom calls,</p> <p>23 document review, and report preparation. In terms</p> <p>24 of the document review, would you be able to tell</p> <p>25 me what documents you're reviewing at any</p>	<p style="text-align: right;">Page 33</p> <p>1 BY MR. SLATER:</p> <p>2 Q. You're not holding yourself out as a</p> <p>3 regulatory expert in this case; correct?</p> <p>4 A. Correct.</p> <p>5 Q. You're not holding yourself out as an</p> <p>6 expert in current good manufacturing practices and</p> <p>7 providing opinions on that; correct?</p> <p>8 A. That's correct.</p> <p>9 Q. You're not holding yourself out as an</p> <p>10 expert in risk assessment process for drugs;</p> <p>11 correct?</p> <p>12 A. That's correct.</p> <p>13 Q. You're not holding yourself out as an</p> <p>14 expert with regard to the content of the organic</p> <p>15 chemistry literature; correct?</p> <p>16 MS. ROSE: Object to the form.</p> <p>17 THE WITNESS: I'm not holding myself out</p> <p>18 as an expert on the content of organic chemistry</p> <p>19 literature?</p> <p>20 BY MR. SLATER:</p> <p>21 Q. Yes, in terms of what was in the</p> <p>22 literature, and when.</p> <p>23 MS. ROSE: Object to the form.</p> <p>24 THE WITNESS: So if -- if I read a paper</p> <p>25 on organic chemistry, so this is, I'm an expert?</p>

<p style="text-align: right;">Page 34</p> <p>1 If you're asking me do I have encyclopedic 2 knowledge of every publication on organic chemistry 3 since the time they started publishing, I don't 4 know that. 5 BY MR. SLATER: 6 Q. You did not do any independent study or 7 analysis of what subjects were in the literature at 8 particular times? You didn't independently 9 evaluate that question; right? 10 MS. ROSE: Object to the form. 11 THE WITNESS: No, I did not. 12 BY MR. SLATER: 13 Q. In looking at your invoice again, on 14 April 10, 2025 it says document review and report 15 preparation. Do you see that entry? 16 A. Yes. 17 Q. I don't see any other entry referring to 18 report preparation. So can I -- rephrase it. Let 19 me start over. I'm sorry. I lost my train of 20 thought. 21 When I look at your invoice, on 22 April 10, 2025 there's a reference to document 23 review and report preparation. There are no 24 subsequent references to report preparation. Does 25 that mean that you had finished preparing your</p>	<p style="text-align: right;">Page 36</p> <p>1 Q. But the report had been completed by 2 April 10th; right? 3 A. Yes. 4 Q. Did you read any depositions as part of 5 your review of materials? 6 A. Yes, I did. 7 Q. Which depositions did you read? 8 A. I read the deposition of Hecht. I read 9 the deposition of Najafi. I read the deposition of 10 Min Li. I read the deposition of somebody else who 11 I can't remember his name from -- from ZHP. And 12 those are the four depositions I can remember 13 reading. 14 Q. Do you recall the role of the person 15 whose name you can't recall at present? 16 A. Yeah, he was like the VP of the company. 17 He was high level. 18 Q. Jun Du? 19 A. I think so. 20 Q. You mentioned him in your report, so I'm 21 trying to help you out. 22 MS. ROSE: Objection, form. 23 MR. SLATER: Object to my help. 24 Actually, that's a good objection. 25 BY MR. SLATER:</p>
<p style="text-align: right;">Page 35</p> <p>1 report as of April 10th, and then you just 2 continued to review documents and had Zoom calls 3 after that time? 4 A. Yes. 5 Q. Why did you continue to review documents 6 and have Zoom calls after your report was done? 7 What was the purpose of that ongoing review and 8 those calls? 9 A. So, you know, I didn't just stop, write 10 the report, put it down, and forget the whole case, 11 right? There were questions I had, thought 12 processes I had that I wanted to go back and 13 clarify further by reading documents in more detail 14 so I could get a clearer picture in my mind of 15 everything that happened, 'cause, you know, there's 16 a lot of documents, and I wanted to read things, 17 especially the DIR, what are they called, deviation 18 investigation report. I wanted to read that in 19 more detail than I had. 20 So I would read the things -- like 21 Najafi and Hecht would reference certain -- certain 22 DIR -- certain places in the DIR. I would read 23 those. But then I went back and read it more 24 thoroughly from start to finish after I wrote the 25 report to get myself up to speed fully.</p>	<p style="text-align: right;">Page 37</p> <p>1 Q. Okay. You can think about it, but as you 2 sit here now, do you feel that probably that fourth 3 person was Jun Du? 4 A. I'd have to look at the name on the 5 deposition. 6 Q. Okay. I'll make a note. I may come back 7 and ask you that maybe after a break. I don't want 8 you to do anything now. 9 A. Okay. 10 Q. Did you read the entire deposition 11 transcripts for every one of those witnesses, or 12 parts of them? 13 A. I think I read the entire deposition 14 transcript. I found it interesting. 15 Q. Do you know how long it took you to read 16 the deposition transcripts of Dr. Hecht? 17 A. Yeah, I was clocking myself at, it was 18 less than a page a minute. It was a little faster 19 than a page a minute, but it wasn't two pages a 20 minute. Something like that, one-and-a-half pages 21 a minute, something like that, it was taking me to 22 read it. 23 Q. You actually have a -- you kept track of 24 the time to read per page? 25 A. Yeah. I would look at -- look -- before</p>

<p style="text-align: right;">Page 38</p> <p>1 I start, I'd look at the clock. Yeah, 25 pages  2 later I'd look at the clock again. How fast am I  3 going, you know?  4 Q. Did you take notes while you were reading  5 these deposition transcripts?  6 A. No.  7 Q. You just read them?  8 A. I read them, yeah.  9 Q. Did you highlight them or put notes on  10 them?  11 A. No. If I'm taking notes, I'm not at the  12 meeting.  13 Q. Did you read the entire deposition  14 transcript of Dr. Najafi?  15 A. I believe I did. But there was two of  16 them. Yeah, there was two of them. I believe I  17 read both of them, one day after the other.  18 Q. Did you read all the deposition  19 transcripts of Min Li?  20 A. I did. There was two of those too.  21 Q. You saw two transcripts of Min Li?  22 A. I saw two different days. I believe  23 there were two different days.  24 Q. Did you read all the testimony of Jun Du,  25 all of his transcripts?</p>	<p style="text-align: right;">Page 40</p> <p>1 today. But between April 30th and today have you  2 spent additional time?  3 A. Yes.  4 Q. What have you done between April 30th and  5 the present?  6 A. I continued with document review and  7 preparation for the deposition.  8 Q. Let's go to exhibit -- I guess we're up  9 to four. Let's go to Exhibit 4, which will be the  10 expert report.  11 MS. ROSE: Doctor, are you able to see  12 Exhibit 4 on --  13 THE WITNESS: Yeah. I'm not -- I'm still  14 trying to bring it up. I can only get as far as  15 Exhibit 3.  16 MR. SLATER: No problem. It's probably  17 just being loaded.  18 THE WITNESS: No, it's still only going  19 as far as Exhibit 3. There we go. Okay, I can see  20 it.  21 BY MR. SLATER:  22 Q. Doctor, do you see in front of you  23 Exhibit 4, which is your expert report?  24 A. I do.  25 Q. And it looks like the body of the report</p>
<p style="text-align: right;">Page 39</p> <p>1 A. For some reason I thought I only had half  2 of that. So I'm -- I'd have to go back and see  3 what things I read for Jun Du.  4 Q. Did you ever hear of Dr. Hecht before you  5 got involved in this case?  6 A. No. And I had him confused with somebody  7 else. Sidney Hecht. There's a Sidney Hecht at the  8 University of Virginia. That's who I thought it  9 was. But his -- what's his first name? His name  10 is --  11 Q. Stephen Hecht.  12 A. Stephen Hecht, yeah. No, he's somebody  13 else. So no, I had never heard of him before this.  14 Sidney, Stephen, you got me confused, you know.  15 Q. There's a series of Zoom calls  16 interspersed. Who are those Zoom calls with? You  17 had told us about the first one with Paul. How  18 about on a going-forward basis, who else did you  19 speak to on Zoom calls?  20 A. So there was Nina -- these are the people  21 I can remember, which I think is complete: Nina,  22 Jessica, Archer and Louis.  23 Q. Is there additional time you have spent  24 after April 30th, which is the last entry on this  25 invoice? Obviously you're here for the deposition</p>	<p style="text-align: right;">Page 41</p> <p>1 itself is ten pages -- ten pages. I see it was  2 signed by you electronically on April 10, 2025; is  3 that correct?  4 A. I'm just scrolling down to page 10. But  5 that sounds like -- yeah, that's -- that's it.  6 That looks like it, yes.  7 Q. You state right above the signature, "I  8 hold these opinions to a reasonable degree of  9 scientific certainty." Do you see that?  10 A. Yes.  11 Q. What does that mean?  12 A. I would say that I used the same  13 scientific rigor to prepare this report that I  14 would use to conduct my research.  15 Q. When you refer to conduct your research,  16 what research are you referring to?  17 A. So to conduct the synthetic -- the  18 chemistry that we did -- or the research that we  19 did at J-STAR, the research that we did at Merck,  20 there was a level of scientific rigor that I  21 applied in that research. And I applied that same  22 level of rigor to preparing this report.  23 Q. And what did that research involve at  24 those times, figuring out how these different  25 substances you were working with could create the</p>

<p style="text-align: right;">Page 42</p> <p>1 desired drug substance?</p> <p>2 A. Working on the synthesis, solving</p> <p>3 problems, yes.</p> <p>4 Q. So if I understand correctly, when you</p> <p>5 were actively working in the lab, you were -- you</p> <p>6 were part of the team that was actually figuring</p> <p>7 out how do we make this substance? That might be</p> <p>8 simple, but is that right?</p> <p>9 A. Yes, what steps do we use, what chemistry</p> <p>10 do we use.</p> <p>11 Q. Going back to your work at Merck. Is</p> <p>12 that what you did at Merck?</p> <p>13 A. Yes.</p> <p>14 Q. Then it looks like you started a company</p> <p>15 called J-STAR; correct?</p> <p>16 A. J-STAR Research, yes.</p> <p>17 Q. And what is J-STAR Research?</p> <p>18 A. What do they do?</p> <p>19 Q. Yep.</p> <p>20 A. Okay. So if I talk too long about</p> <p>21 this --</p> <p>22 Q. Give me -- let me cut you off. Tell me</p> <p>23 at a high level what J-STAR does, and then we'll</p> <p>24 get into a little more as we talk today.</p> <p>25 A. Okay. So J-STAR -- so at Merck I worked</p>	<p style="text-align: right;">Page 44</p> <p>1 MS. ROSE: If you could wait, Doctor, for</p> <p>2 a second. I'm trying to get in there quick.</p> <p>3 THE WITNESS: All right.</p> <p>4 MS. ROSE: If you could give me a second</p> <p>5 to object, like Mr. Slater said at the beginning of</p> <p>6 the deposition, that would be very helpful. Thank</p> <p>7 you.</p> <p>8 THE WITNESS: Okay. So it wasn't the</p> <p>9 manufacturer that provided. It was -- it was the</p> <p>10 owner of the intellectual property. And they would</p> <p>11 sometimes provide us with a synthesis, sometimes</p> <p>12 provide us with a target and no synthesis, or</p> <p>13 partially a synthesis. Usually they had some</p> <p>14 synthesis problem they needed solved that we solved</p> <p>15 for them.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. When you say the owner of the</p> <p>18 intellectual property as opposed to the</p> <p>19 manufacturer, can you explain to me the</p> <p>20 distinction, please?</p> <p>21 A. Yes. So the owner -- the manufacturer is</p> <p>22 just another contract lab like J-STAR, okay? I</p> <p>23 didn't own the intellectual property. The</p> <p>24 manufacturer doesn't own the intellectual property.</p> <p>25 There's an entity, that's the biotech, they -- and</p>
<p style="text-align: right;">Page 43</p> <p>1 in the department of process research. That was</p> <p>2 one department at Merck. There was a medicinal</p> <p>3 chemistry department. There was the department of</p> <p>4 the process research. So J-STAR was the department</p> <p>5 of process research that a company could outsource</p> <p>6 to to get that kind of work done.</p> <p>7 If you didn't have your own department</p> <p>8 and didn't want to spend the money to build it and</p> <p>9 hire the people, you could rent it from us. And</p> <p>10 when you were done, you handed back the keys and</p> <p>11 stopped paying for it. That was the product that I</p> <p>12 was selling.</p> <p>13 Q. So J-STAR was a contract process research</p> <p>14 laboratory?</p> <p>15 A. Contract research laboratory, CRO.</p> <p>16 Q. When J-STAR would be contracted for a</p> <p>17 specific project, would the manufacturer -- what</p> <p>18 would the manufacturer provide to J-STAR in order</p> <p>19 to get J-STAR going? Would it just be a general</p> <p>20 idea? Would it be actual synthesis analysis?</p> <p>21 Would it be actual development ideas? What would</p> <p>22 they give you to get started?</p> <p>23 MS. ROSE: Object to form.</p> <p>24 THE WITNESS: All of the above. Oh,</p> <p>25 sorry.</p>	<p style="text-align: right;">Page 45</p> <p>1 they're funded by venture capital. They own the</p> <p>2 intellectual property. And they contract out all</p> <p>3 the aspects of the development. So I consider the</p> <p>4 manufacturer another contract -- contractor in the</p> <p>5 supply chain.</p> <p>6 Q. Would that apply to Merck? For example,</p> <p>7 would you see Merck as a manufacturer in that</p> <p>8 context as you define those terms?</p> <p>9 MS. ROSE: Object to the form.</p> <p>10 THE WITNESS: So Merck is a different</p> <p>11 beast. Merck would never be a customer -- not</p> <p>12 really be a customer of mine. Merck had everything</p> <p>13 internally. They were the owner of the</p> <p>14 intellectual property. They had the process</p> <p>15 research group, and they had the manufacturing</p> <p>16 assets and drug product and marketing. They had</p> <p>17 everything, soup to nuts. They didn't need to</p> <p>18 contract out to anybody. They had it all. All the</p> <p>19 big pharmas are like that.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. Okay. And that's helpful, 'cause I</p> <p>22 wanted to understand who your client base was at</p> <p>23 J-STAR. And I understood that maybe you were</p> <p>24 working with companies like Merck or Johnson &amp;</p> <p>25 Johnson or other companies that actually, as you</p>



<p style="text-align: right;">Page 46</p> <p>1 said, have -- have all of these different facets 2 internally. But those would not have been your 3 customers at J-STAR? 4 A. So Merck sent us a little bit of work. 5 We had some work with large companies that had all 6 those things. But the bulk of our work was with 7 smaller companies, merging pharma companies. 8 Q. When you say that you would be provided 9 the -- I'm going to call it the assignment or 10 contract with the owner of the intellectual 11 property -- what would they be giving to you to get 12 you started? How would that typically happen? 13 A. They would give me a tech package, and 14 the tech package would outline usually the target, 15 whatever synthesis they had in place at that point, 16 and all the requirements they wanted me to take 17 care of. And they wanted me to quote on what it 18 would cost to do all that, and a timeline. 19 Q. When you refer to the target, what does 20 that mean? 21 A. The target is the API. 22 Q. In terms of what it was intended to be 23 able to do? Let me ask it differently. 24 When you say the target is the API, 25 just tell me exactly what it is that that means to</p>	<p style="text-align: right;">Page 48</p> <p>1 process whereby you could actually manufacture the 2 API? 3 A. Yes. 4 Q. So in other words, the how to? 5 A. The how to, yeah. 6 Q. In doing some research, it looked like 7 your company was purchased or acquired by another 8 company called Porton, P-O-R-T-O-N. Is that 9 correct? 10 A. Yes. 11 Q. And from my reading, it looks like that 12 took place in 2017? 13 A. Yes. 14 Q. What is Porton? 15 A. So Porton's a bigger fish. They're a 16 manufacturer. And so they were -- they're based in 17 China, central China, next to outer Mongolia. They 18 wanted to have a presence in the United States. To 19 get that presence, they bought us. 20 Q. Did your company's name change at that 21 point, or were you just then a wholly-owned 22 subsidiary of Porton? 23 A. We were a wholly-owned subsidiary of 24 Porton. 25 Q. Did Porton have control over your</p>
<p style="text-align: right;">Page 47</p> <p>1 you. I don't want to inartfully describe it. 2 A. So that's the chemical structure of the 3 API. I would get -- I would get provided the 4 chemical structure. And the chemical structure of 5 the intermediates and the steps they used to 6 convert the intermediates to the API. Chemical 7 structure is all I got. 8 Q. And you would then take that chemical 9 structure and attempt to synthesize it into an 10 actual API that could be produced in the lab? 11 A. So I would take their synthesis and 12 eval -- we would evaluate it to see if it was 13 practical for scale up to kilogram scale. And if 14 it wasn't, we would suggest to the customer you 15 need to fix this step, you need to look at this 16 here, you need to do this, you need to do that. 17 But by and large, yes, I would take 18 the chemical structures, I would buy the starting 19 materials from a chemical company or raw materials 20 supplier, and I would buy the reagents to do the 21 chemistry, and we would do the conversions. But 22 there was -- there was a lot of research that went 23 into it before we started making material. 24 Q. When you say there was a lot of research, 25 would that be the research into developing a</p>	<p style="text-align: right;">Page 49</p> <p>1 operations as the owner? 2 A. Yes, they did. 3 Q. Did your company develop substances for 4 manufacture in China? 5 A. Yes, we did. 6 Q. What substances were those? 7 A. So that's kind of proprietary 8 information, but -- and it didn't happen all the 9 time, but there were certain cases where somebody 10 wanted a metric ton of an intermediate and the 11 synthesis wasn't even capable of making a gram. So 12 we'd work out the process in the United States, and 13 then we'd send that process to the chemists in 14 China, and they would make the metric ton out of 15 it. So that was the idea behind the purchase. 16 So we would get the business on the 17 small scale, work it out or send it directly to 18 China. That was the idea. 19 Q. So in those cases you would figure out at 20 the lab scale how this could be manufactured and 21 think it through and then send them to -- that 22 process and they could then attempt to manufacture 23 at a larger scale in China when that happened? 24 A. Yes. So when that happened, they didn't 25 need us to make five kilos, 'cause they can</p>

<p style="text-align: right;">Page 50</p> <p>1 make -- so we would give them the recipe. Here's  2 the recipe, you know, A, B, C, D instructions.  3 Here it is. You can take it from -- and we would  4 give it to a technical group in China, and they  5 would take over from there.  6 Q. Did you travel to China at any time as  7 part of this work?  8 A. I did.  9 Q. How often?  10 A. Two or three times a year.  11 Q. Why was that?  12 A. So they would have, like, corporate board  13 meetings, and they just liked to be face to face,  14 so -- and they had operations all over the world.  15 It wasn't just New Jersey. They had operations in  16 Switzerland. They had operations in Belgium.  17 And -- and all of those people would get together  18 for a board meeting. So I'd get to meet all those  19 people. We'd have dinner together.  20 MR. SLATER: I'm happy to keep going. I  21 know, Nina, sometimes you like to take breaks.  22 It's up to you. This would be a good breaking  23 point. But if you want to keep going, I can go  24 without stopping.  25 MS. ROSE: You hit one hour on the nail,</p>	<p style="text-align: right;">Page 52</p> <p>1 A. Hold on. I gotta scroll all the way up  2 to the top, 'cause I was at the signature page.  3 The first paragraph, "I have been asked." That  4 one?  5 Q. Exactly.  6 A. Okay.  7 Q. Looking at the first paragraph on page 1  8 you wrote, "I've been asked to review and respond  9 to certain statements made in expert reports  10 submitted by Drs. Ramin Najafi and Stephen Hecht in  11 connection with this litigation." And I just want  12 to stop there.  13 When you refer to reviewing and  14 responding, did you understand that your role here  15 was to look at what they said and then give your  16 reaction to what they were saying?  17 A. Yeah, my role was to give my opinion on  18 their opinions.  19 Q. And that's what you say in the next  20 sentence, specifically, "I have been asked to  21 evaluate opinions by Drs. Najafi and Hecht  22 regarding the state of knowledge in the field of  23 chemistry and, in particular, by chemists involved  24 in the development and manufacture of drug  25 substances regarding the potential for formation of</p>
<p style="text-align: right;">Page 51</p> <p>1 Adam. So, yeah, it's a perfect time for a break.  2 THE WITNESS: Okay, great. Be back in  3 two minutes.  4 MR. SLATER: Let's give it five. See you  5 soon.  6 THE VIDEOGRAPHER: We're off the  7 record -- would you like to go off the record?  8 THE WITNESS: Yeah, five minutes, right?  9 I heard you.  10 MS. ROSE: Yeah, just five. Mute --  11 THE VIDEOGRAPHER: We're off the  12 record --  13 MS. ROSE: We're off the record.  14 THE VIDEOGRAPHER: No. We're off the  15 record at 10:44 a.m. Thank you.  16 (Break taken.)  17 THE VIDEOGRAPHER: We're back on the  18 record at 11:05 a.m.  19 BY MR. SLATER:  20 Q. Okay. Doctor, I'm looking at your report  21 now which we marked as Exhibit 4. Do you have that  22 in front of you?  23 A. I'm going to get -- yes, I do.  24 Q. Okay. I'm looking right at the first  25 paragraph.</p>	<p style="text-align: right;">Page 53</p> <p>1 nitrosamines in valsartan drug substance  2 manufactured by ZHP prior to the discovery of trace  3 amounts of NDMA in the drug substance in 2018."  4 And that's -- that's -- is that a good  5 explanation of what your role was here and what you  6 brought your expertise in on?  7 A. Yes.  8 Q. And again, you didn't do anything  9 independent in terms of research. As you told me  10 before, you looked at their depositions, you looked  11 at their reports, you looked at the documents you  12 were given, and reacted to that information;  13 correct?  14 A. Yes.  15 Q. And when you provided your opinions based  16 on your evaluation, it's my understanding you were  17 basing that on your experience based on your work  18 that you've done over the years in the chemistry  19 field; correct?  20 A. Yes.  21 Q. You were not applying, that I saw from  22 the report, any specific standard or outside  23 criteria to measure what was known or should have  24 been known. You based it on what you know based on  25 your work and your own experience; correct?</p>



<p style="text-align: right;">Page 54</p> <p>1 MS. ROSE: Objection, form.  2 BY MR. SLATER:  3 Q. Let me ask it differently. In terms of  4 the standard that you applied in evaluating what  5 Drs. Najafi and Hecht said, am I correct that you  6 measured what they said against what you're  7 familiar with from your work and what you know from  8 your practice of organic chemistry or synthesis as  9 you described it? Do I understand that correctly?  10 A. Yes. I mean, it's in particular to  11 impurities and how impurities are identified.  12 That's kind of the focus of my opinion, how you  13 identify -- how you first notify and how you  14 identify impurities. That's what I'm referring to,  15 yes.  16 Q. And in terms of how that is done and what  17 needs to be looked for, you base that on your own  18 experience working in a lab; is that correct?  19 A. I base it on my -- on my experience with  20 all the APIs I've ever developed over 35 years.  21 Somebody's trying to come in. That might not be  22 good, unless that's just the mailman. Hold on.  23 Just give me a sec.  24 MS. ROSE: Should we go off the record?  25 MR. SLATER: Sure.</p>	<p style="text-align: right;">Page 56</p> <p>1 Q. Did you read every single exhibit from  2 every single deposition that's listed here?  3 A. No.  4 Q. Do you know which exhibits you read and  5 which you didn't read?  6 A. I can't recall off the top of my head.  7 Q. Does this report contain all of the  8 opinions that you have formed in this case?  9 A. Yes.  10 Q. And you understand that's the purpose of  11 the report being written, is to give notice to us,  12 the plaintiffs, as to what your opinions are so we  13 can understand what opinions you may give at trial.  14 You understood that; right?  15 A. Yes.  16 Q. In the course of the report you talked  17 about certain facts. You cited to certain  18 testimony, certain parts of the expert reports,  19 certain documents. Are those the specific items  20 that you found to be most important to you in  21 forming your opinion here?  22 A. Yeah, if I'm citing something,  23 it's -- it's cherry-picked most important documents  24 to me, yes.  25 Q. Let's go to page 3 if we could.</p>
<p style="text-align: right;">Page 55</p> <p>1 THE WITNESS: No, I think we're okay.  2 MR. SLATER: No, no, we're back.  3 THE WITNESS: My concern is that one of  4 my three-year-old grandkids is going to come  5 tearing through here and -- you know, and  6 interrupting. No, it's okay. That's not  7 happening.  8 BY MR. SLATER:  9 Q. If they come in, we gotta put them under  10 oath.  11 A. I know. That's why I don't want them  12 coming in.  13 Q. Let's go to the second page of your  14 report, please.  15 A. Okay. Okay, so you're going over there.  16 Okay. Second page.  17 Q. You have a heading that says Basis for  18 Opinions. And that's listing an overview of what  19 you reviewed; correct?  20 A. Yes.  21 Q. Now in reviewing this you refer to, for  22 example, the deposition or the depositions of  23 Dr. Hecht and exhibits. Do you see those bullet  24 points at the bottom of the page?  25 A. Yes.</p>	<p style="text-align: right;">Page 57</p> <p>1 A. Okay.  2 Q. You state in section three, Opinions,  3 "Over the course of my 38 years of work in the  4 pharmaceutical and drug development industry, I've  5 been involved in the development of more than 250  6 APIs." I'm going to stop there.  7 Were these APIs new drugs or at least  8 intended to be new drugs, or were they generics in  9 the sense of trying to be the generic equivalents  10 of something else that was already a brand drug?  11 A. I would say greater than 99 percent of  12 them were new branded pharmaceutical -- were going  13 to be new branded pharmaceuticals, new drugs.  14 Q. You state in the second sentence of that  15 section, "In developing every one of the API  16 substances I worked with over the course of my  17 career, I and my team made an effort to anticipate  18 impurities that may form in the production of the  19 drug substance." Do you see where I'm reading?  20 A. Yes.  21 Q. When you say an effort to anticipate  22 impurities that may form in the production of drug  23 substance, what does that mean?  24 A. So I would look at the chemical  25 structure, I'd look at the reaction we were doing,</p>

<p style="text-align: right;">Page 58</p> <p>1 and the conditions, and if I could see a possible 2 reaction pathway that I didn't want to happen that 3 would generate an impurity, I would try to 4 anticipate those. I would try -- I would try to 5 figure out what could go wrong in every step. Me 6 and my team would do that. 7 Q. Did you do so based on your experience 8 and knowledge? 9 A. Yes. 10 Q. Did you do independent literature or 11 other scientific research as part of that? 12 A. Sometimes. 13 Q. You indicate, "For example, after 2015 14 ICH M7 -- addressing genotoxic impurities -- was 15 adopted by the FDA, the potential formation of 16 genotoxic impurities was a consideration with 17 respect to every API that we developed"; correct? 18 A. Correct. 19 Q. What's ICH M7? 20 A. So I'm not the regulatory expert; I think 21 we established that in the beginning. But my 22 understanding of ICH M7 is that that's the guidance 23 that came out specifically relating to genotoxic 24 impurity presence in API. 25 Q. Did you ever read the ICH M7?</p>	<p style="text-align: right;">Page 60</p> <p>1 A. Yes. 2 Q. You don't have to know that it's 3 definitely going to form before you start to be 4 concerned; right? 5 MS. ROSE: Object to the form. 6 THE WITNESS: It's also not a hundred 7 percent going to cover every situation. It's only 8 the ones you can think of. 9 MR. SLATER: Move to strike. 10 BY MR. SLATER: 11 Q. My question is this -- 12 MS. ROSE: Adam, I'm sorry -- 13 MR. SLATER: I did it again. I'm sorry. 14 I apologize. I withdraw that. 15 BY MR. SLATER: 16 Q. I wish someone was here to hit me with a 17 ruler, you know, on the hand. 18 A. We are. 19 Q. When you refer to the potential 20 formation, that's what you need to be concerned 21 about. It's not that you have to know something is 22 going to form before you have a concern; correct? 23 MS. ROSE: Object to the form. 24 THE WITNESS: Yeah, you want to -- if you 25 know it's in there, if you put it in there, for</p>
<p style="text-align: right;">Page 59</p> <p>1 A. I did. 2 Q. Did you ever read the prior versions 3 before 2015? 4 A. The guide -- the draft guidance? 5 Q. The draft of ICH M7 going back to 2013, 6 did you read that? 7 A. I had a hard time finding that. I don't 8 know if I ever found it or could read it. I don't 9 remember. 10 Q. Do you understand what a genotoxic 11 impurity is? 12 A. I have my understanding. 13 Q. What's your understanding? 14 A. It's typically an alkylating agent that 15 reacts with DNA and causes a disruption in the 16 D -- in the DNA structure, change of base. 17 Q. You referred to the potential formation 18 of genotoxic impurities; correct? 19 A. I'm trying to see where it says -- 20 Q. That same sentence I asked you about. 21 A. Yeah. 22 Q. And you would agree with me 23 that's -- that's what the developer of a drug 24 substance would need to be aware of potential 25 formation; right?</p>	<p style="text-align: right;">Page 61</p> <p>1 example, put it in there, you know it's going to be 2 there, and things you can think of that 3 could potentially form. Again, the emphasis in 4 that sentence is things you can think of. It 5 doesn't cover things you can't think of or you 6 haven't -- you didn't think of. 7 BY MR. SLATER: 8 Q. Do you know what standards applied to the 9 people at ZHP who were the process chemists in 10 terms of what the standard was for them in terms of 11 what they were supposed to do in order to evaluate 12 potential formation of genotoxic impurities? Do 13 you know what standards applied to them? 14 MS. ROSE: Object. Outside the scope of 15 his expertise. 16 THE WITNESS: And the answer is no, I do 17 not. 18 BY MR. SLATER: 19 Q. So if I'm understanding, you did not 20 apply any specific, for example, published standard 21 or standards in evaluating what the people at ZHP 22 could or should have known about with regard to 23 potential impurities, specifically genotoxic 24 impurities; correct? 25 MS. ROSE: Object to the form.</p>

<p style="text-align: right;">Page 62</p> <p>1 THE WITNESS: No. I didn't know what 2 standards they were applying. I couldn't possibly 3 have done that. 4 BY MR. SLATER: 5 Q. And you didn't apply any specific 6 standard in evaluating this material; correct? 7 MS. ROSE: Object to the form. 8 THE WITNESS: In evaluating the valsartan 9 material? 10 BY MR. SLATER: 11 Q. The material in this case, you didn't 12 apply a specific standard or standards in reaching 13 your opinions; correct? 14 MS. ROSE: Object to the form. 15 THE WITNESS: I didn't -- I didn't apply 16 any known risk analysis, formal risk analysis, to 17 it. 18 BY MR. SLATER: 19 Q. For example, you didn't go back, for 20 example, to any of the FDA or ICH guidances with 21 regard to genotoxic impurities, look for what they 22 said is supposed to be done in terms of assessing 23 the risk for genotoxic impurities, and apply those 24 standards? That's not something you did; correct? 25 MS. ROSE: Object, outside the scope.</p>	<p style="text-align: right;">Page 64</p> <p>1 BY MR. SLATER: 2 Q. Doctor, you said that if you don't 3 anticipate it, you can't control it a moment ago. 4 Do you remember that? 5 A. If you don't anticipate it, you can't put 6 in protocols to control it. It's a little more 7 than that, actually. If you don't anticipate it, 8 and you don't see it on a chromatogram, you don't 9 see any evidence of it, so you didn't think of it, 10 and you don't see any evidence in your data that 11 it's there, yeah, you're going to miss that one. 12 Q. And when you say if you don't anticipate 13 it, you're not saying that in all cases the failure 14 to anticipate that there's a potential formation of 15 a genotoxic impurity is excusable? You're not 16 saying that; right? 17 A. In all cases it's excusable if you don't 18 anticipate it. No, I'm not saying that. 19 Q. Because the -- based on your experience 20 in your lab, you would give some thought to it and 21 you would hope that you anticipate potential 22 impurities; right? 23 MS. ROSE: Object to the form. 24 THE WITNESS: Yes, so that's -- I don't 25 know how to put it -- a nerve-wracking situation,</p>
<p style="text-align: right;">Page 63</p> <p>1 THE WITNESS: I read the guidance to see 2 what the -- the levels should be and how you would 3 determine them. In all cases, things -- the way I 4 read the guidance, things you know about, or things 5 you can anticipate, you have to control. But the 6 way I read it, if you didn't anticipate it, you 7 couldn't possibly control it. That's the way I 8 read the guidance. 9 BY MR. SLATER: 10 Q. Is that the M7 you're talking about? 11 A. Yes. 12 Q. In evaluating what ZHP knew or should 13 have known, did you apply their internal standard 14 operating procedures or internal protocols? 15 A. Did I apply ZHP's internal standard 16 operating procedures? 17 Q. Correct. 18 A. No. I just gotta take a minute. Can I 19 come back in a minute? 20 MR. SLATER: Can we go off? 21 THE VIDEOGRAPHER: We're off the record 22 at 11:22 a.m. 23 (Break taken.) 24 THE VIDEOGRAPHER: We're back on the 25 record at 11:25 a.m.</p>	<p style="text-align: right;">Page 65</p> <p>1 right? Because you have to anticipate it. You 2 have to hope you see it. And if you don't, you're 3 going to miss it. 4 BY MR. SLATER: 5 Q. Do you know -- well, rephrase. I think 6 you've already said that you don't know and didn't 7 apply any particular standards in terms of what the 8 people at ZHP were supposed to do to try to 9 anticipate potential genotoxic impurities; correct? 10 MS. ROSE: Object to the form. 11 THE WITNESS: No, I don't know what 12 protocols they were supposed to do or -- I know 13 what they did in the DIR afterwards, but not 14 beforehand. 15 BY MR. SLATER: 16 Q. And you don't know what they were 17 supposed to do based on any regulatory standards or 18 any internal protocols. That's not something you 19 took into account; right? 20 MS. ROSE: Object to the form. 21 THE WITNESS: That's correct, I did not 22 take that into account. 23 BY MR. SLATER: 24 Q. In terms of what could have been known 25 here, you base that on your own experience and</p>

<p style="text-align: right;">Page 66</p> <p>1 knowledge from your own work. That was -- that was 2 your criteria; correct? 3 MS. ROSE: Object to the form. 4 THE WITNESS: I based it on my knowledge 5 and what I thought the knowledge would be for the 6 people I worked with over the years, and also on 7 the fact that this -- these amendments that the DMF 8 were reviewed by chemists at the FDA and the EMEA. 9 So I got insight into what they were thinking also 10 from their responses to those amendments. 11 So it was three -- really three 12 different things. It wasn't just my own opinion. 13 It was -- I mean, there was people out there 14 reviewing those documents with an eye towards 15 safety who didn't notice this. 16 BY MR. SLATER: 17 Q. You agree with me that ZHP was 18 responsible for the quality of its valsartan API at 19 all times? 20 A. I agree that they were responsible for 21 the quality and they were responsible for knowing 22 the process. But when I say the FDA reviewed it 23 and missed it, I'm not saying they were 24 responsible. I'm saying they did it -- I could 25 understand what they were thinking. That's all I'm</p>	<p style="text-align: right;">Page 68</p> <p>1 support your opinion, is that the statements that 2 you quoted in your report regarding whether or not 3 people were aware of the presence of nitrosamines 4 in the valsartan drug product before it was 5 disclosed in June 2018? 6 A. I'm not exactly sure. There was a -- you 7 know, there was a statement that came out about the 8 GC mass spec method they developed, and this was 9 not easy to do because they're difficult to see. 10 So it was statements like that that the FDA came 11 out with that I thought supported the position that 12 this was -- this was a difficult wrinkle to see. 13 Q. Did you also notice that the FDA issued a 14 warning letter to ZHP and put them on an import 15 alert? 16 A. Yes, I did. 17 Q. Did you see that the FDA was critical of 18 ZHP's evaluation of this question of the potential 19 impurities when they were developing this 20 manufacturing process? 21 A. So -- 22 MS. ROSE: Object to the form. 23 THE WITNESS: -- my recollection of that 24 warning letter comes from Najafi's report. And 25 when I read through each one of them -- there was</p>
<p style="text-align: right;">Page 67</p> <p>1 saying, is what they were thinking, and they didn't 2 see it. I'm not saying they were responsible. I'm 3 just saying what they were thinking. That's all 4 I'm doing with that information. 5 Q. In forming your opinion here, are you 6 relying on statements by the FDA? 7 A. I wouldn't say -- I'm not relying on the 8 FDA statements in a major way. I mean, in a 9 supporting way, yes, there's a lot of statements 10 the FDA made that support -- support my opinion 11 that this was not an -- not an obvious and easy 12 thing to catch. 13 Q. Do you know whether or not ZHP was 14 expected to be aware of this risk even though it 15 wasn't obvious and easy to catch, as you said? 16 MS. ROSE: Object to the form. 17 THE WITNESS: Do I know if ZHP should 18 have been -- what exactly did you say? 19 BY MR. SLATER: 20 Q. I'll ask it again. Do you know whether 21 ZHP was responsible to identify the potential risk 22 of forming these genotoxic impurities even if it 23 was not, to quote you, obvious and easy to catch? 24 A. I don't know the answer to that question. 25 Q. When you say that the FDA statements</p>	<p style="text-align: right;">Page 69</p> <p>1 like eight of them -- it didn't look to me like any 2 one of those problems resulted in them missing this 3 impurity. And there were other problems with, 4 like, reporting structures. 5 And they were not -- there wasn't a 6 single problem I saw in the warning letter that I 7 could directly attribute to them not observing this 8 impurity. So it was -- it was -- it wasn't -- it 9 was irrelevant. I hate to say that their warning 10 letter was irrelevant, but it was irrelevant to my 11 forming this opinion. 12 Q. So I understand, you felt that the 13 contents of the warning letter was irrelevant to 14 the issue that you were opining on? 15 MS. ROSE: Object to the form. Misstates 16 the witness. 17 THE WITNESS: Yes, it was irrelevant to 18 the issue that I was providing an opinion on, yes. 19 BY MR. SLATER: 20 Q. Did you read the warning letter or just 21 the account of it in Dr. Najafi's report? 22 A. I just read the account. 23 Q. Can you pull up the next exhibit, please? 24 We're up to five now. We're going to put the 25 warning letter in. Exhibit 5 dated November 29,</p>

<p style="text-align: right;">Page 70</p> <p>1 2018. 2 A. That's Exhibit 5? 3 Q. Yes, that's what I'm told. 4 A. Okay. I see it. 5 Q. And you have never read this letter 6 before right now; right? 7 A. I don't think so, no. 8 MS. ROSE: Hold on, Adam. Sorry. I'm 9 unable to see the exhibit. 10 MR. SLATER: It's on the screen. Oh, 11 you're saying in your -- 12 MS. ROSE: Yeah. Sorry. Give me one 13 second. 14 MR. SLATER: No problem. 15 MS. ROSE: I might have to reload it. 16 MR. SLATER: Hey, I can't criticize you, 17 'cause if somebody told me to go find it in chat or 18 whatever, I couldn't do it if you put a gun to my 19 head, so... 20 MS. ROSE: I have it now. Thank you. 21 MR. SLATER: Okay. 22 BY MR. SLATER: 23 Q. So Doctor, you can see this is the 24 November 29, 2018 warning letter that was issued. 25 And it's actually written to Mr. Jun Du, executive</p>	<p style="text-align: right;">Page 72</p> <p>1 Q. 42. 2 A. 42. Which page of the document? So 3 there's a page number on the top of the document on 4 the right. You see that? 5 Q. Yeah. It's page 4. 6 A. Page 4. 7 Q. Sorry about that. I had a Post-it note 8 over that. 9 MS. ROSE: Just for clarification, I 10 think the doctor was right. This Bates number ends 11 in 62. 12 MR. SLATER: It does? Oh, it must be a 13 different version of it. Okay. Sorry. You know 14 what? Multiple versions. So... 15 THE WITNESS: That's helpful. 16 MR. SLATER: Okay. 17 BY MR. SLATER: 18 Q. Doctor, I'll start over. Looking now at 19 page 4 of the warning letter, you see paragraph 20 number two titled Failure to -- rephrase. 21 Looking now at page 4 of the warning 22 letter, section two is titled, "Failure to evaluate 23 the potential effect that changes in the 24 manufacturing process may have on the quality of 25 your API." Do you see that?</p>
<p style="text-align: right;">Page 71</p> <p>1 vice president of ZHP. Do you see that? 2 A. Yes. 3 Q. And by the way, we talked earlier. Were 4 you able to refresh yourself as to whether Jun Du 5 was the fourth person whose deposition you read? 6 A. I think he was, yes. 7 Q. If you go down to the second paragraph, 8 it says, "This warning letter summarizes 9 significant deviations from current good 10 manufacturing practice, CGMP, for active 11 pharmaceutical ingredients, API." Do you see that? 12 A. Yes. 13 Q. Then you already told me you're not 14 giving any opinions on good manufacturing 15 practices; right? 16 A. Right. 17 Q. Let's go to page, I think it's the fourth 18 page of this letter. The Bates number in the 19 bottom right is 42. It's paragraph number two. 20 A. Page on the right? 21 Q. Paragraph number two. It's the fourth 22 page in. I was referring to the Bates number, the 23 little numbers on the bottom right where the last 24 two digits are 42. 25 A. Yeah, 62?</p>	<p style="text-align: right;">Page 73</p> <p>1 A. I see that. 2 Q. This states, "In November 2011, you 3 approved a valsartan API process change." And then 4 in parentheses PCRC-11025 -- "that included the use 5 of the solvent DMF. Your intention was to improve 6 the manufacturing process, increase product yield, 7 and lower production costs. However, you failed to 8 adequately assess the potential formation of 9 mutagenic impurities when you implemented the new 10 process, specifically, you did not consider the 11 potential for mutagenic or other toxic impurities 12 to form from DMF degradents, including the primary 13 DMF degradent dimethylamine." So I'm going to stop 14 there. Do you see what I just read? 15 A. Yes. 16 Q. The information I just read to you you 17 were not aware of before I'm reading it to you 18 right now; correct? 19 MS. ROSE: Object to the form. 20 THE WITNESS: I don't know if this has 21 showed up in any of the testimony that Najafi and 22 Hecht gave, but okay, let's say I wasn't aware of 23 it, yes. 24 BY MR. SLATER: 25 Q. You would agree that that statement by</p>



<p style="text-align: right;">Page 74</p> <p>1 the FDA is significant; right?</p> <p>2 MS. ROSE: Object to the form. He's not</p> <p>3 a regulatory expert, and said he can't comment on</p> <p>4 the FDA.</p> <p>5 THE WITNESS: So this is another example</p> <p>6 of a hindsight, Monday morning quarterbacking</p> <p>7 comment, okay? So everybody knows after the fact</p> <p>8 where this -- there was a mutagenic and what it was</p> <p>9 and where it came from. So when they say you did</p> <p>10 not consider the potential for mutagenic</p> <p>11 impurities, it's -- it didn't -- it's -- it didn't</p> <p>12 present itself as something to consider. It's not</p> <p>13 that they didn't consider it. It never presented</p> <p>14 itself as something you should consider. So it</p> <p>15 still doesn't change my opinion.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. You disagree with the statement by the</p> <p>18 FDA that ZHP failed to adequately assess the</p> <p>19 potential formation of mutagenic impurities when</p> <p>20 they implemented the new process, or is that beyond</p> <p>21 the scope of your opinion?</p> <p>22 MS. ROSE: Object to the form.</p> <p>23 THE WITNESS: Yeah, I mean, it has to be</p> <p>24 beyond the -- I don't agree -- it's beyond -- it's</p> <p>25 really beyond the scope, because I don't know</p>	<p style="text-align: right;">Page 76</p> <p>1 think of it, they didn't do the investigation. So</p> <p>2 factually, I guess that sentence is probably true.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. You said if they thought of it, they</p> <p>5 would have investigated it. Wouldn't the truer</p> <p>6 statement be if they thought of it, they would have</p> <p>7 been required to investigate it?</p> <p>8 MS. ROSE: Object to the form.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. Let me ask it differently. If ZHP had</p> <p>11 realized the potential for mutagenic or other toxic</p> <p>12 impurities to form from DMF degradents, including</p> <p>13 the primary DMF degradent dimethylamine, they would</p> <p>14 have been required to investigate it; correct?</p> <p>15 MS. ROSE: Object to the form. Outside</p> <p>16 the scope.</p> <p>17 THE WITNESS: I believe it's both. They</p> <p>18 would have done it, and they would have been</p> <p>19 required to do it. They would have wanted to do</p> <p>20 it, and they would have been required to do it.</p> <p>21 Both.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. You don't know whether they -- whether</p> <p>24 ZHP actually did evaluate that question at any</p> <p>25 point before June 2018; right?</p>
<p style="text-align: right;">Page 75</p> <p>1 exactly what they did inside of ZHP to -- for the</p> <p>2 assessment. But it's -- it's beyond the scope,</p> <p>3 let's just say that.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. This states in the next sentence, "You</p> <p>6 did not consider the potential for mutagenic or</p> <p>7 other toxic impurities to form from DMF degradents,</p> <p>8 including the primary DMF degradent,</p> <p>9 dimethylamine." Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. You have no reason to dispute that</p> <p>12 factual statement by the FDA; correct?</p> <p>13 MS. ROSE: Object to the form.</p> <p>14 THE WITNESS: So are you saying I don't</p> <p>15 dispute the fact of that statement?</p> <p>16 BY MR. SLATER:</p> <p>17 Q. You have no basis to dispute that factual</p> <p>18 statement by the FDA which they made after doing an</p> <p>19 inspection at ZHP; correct?</p> <p>20 MS. ROSE: Object to the form.</p> <p>21 THE WITNESS: I really can't answer that,</p> <p>22 because I don't know what they considered, but --</p> <p>23 so you have to infer -- I would infer that if they</p> <p>24 thought of that happening, they would have</p> <p>25 investigated it. So they -- because they didn't</p>	<p style="text-align: right;">Page 77</p> <p>1 A. I do not.</p> <p>2 Q. You agree with me that the primary DMF</p> <p>3 degradent is dimethylamine? You agree with me on</p> <p>4 that as a chemist; right?</p> <p>5 A. I guess there's really two. If you're</p> <p>6 going to have dimethylamine around, you're going to</p> <p>7 have CO as well, and formic acid. So there's both.</p> <p>8 Q. In your work over all the years that</p> <p>9 you've been a process chemist, did you ever work</p> <p>10 with DMF?</p> <p>11 A. All the time.</p> <p>12 Q. And were you aware that the DMF could</p> <p>13 include as an impurity dimethylamine?</p> <p>14 A. I might have encountered that over the</p> <p>15 years, but it never enters into my mind when I</p> <p>16 suggest DMF as a solvent. I never think of it.</p> <p>17 Q. That's your personal practice; correct?</p> <p>18 A. And all the people I worked with.</p> <p>19 Q. When you worked with DMF, did you</p> <p>20 familiarize yourself with the potential impurities</p> <p>21 that DMF could introduce to a manufacturing</p> <p>22 process?</p> <p>23 A. When I did --</p> <p>24 Q. When you worked with DMF, did you</p> <p>25 familiarize yourself with the potential impurities</p>

<p style="text-align: right;">Page 78</p> <p>1 that the DMF could introduce to the manufacturing 2 process? 3 A. No. 4 Q. In all the time that you worked with DMF, 5 did you ever introduce DMF into a manufacturing 6 process where it would come into contact with 7 sodium nitrite or nitrous acid? 8 A. No. I don't believe -- 9 Q. Have you ever or just -- 10 MS. ROSE: I'm sorry, Adam. The witness 11 wasn't done answering. 12 BY MR. SLATER: 13 Q. Not trying to interrupt. Go ahead. 14 A. I can't remember the last -- I think the 15 last time I worked with sodium nitrite was 40 years 16 ago in graduate school. Over 40 years ago. Almost 17 never use it, not in pharmaceutical industry. 18 Q. Was that deliberate in the sense of 19 trying to avoid a risk, or was it just that's how 20 it went? 21 A. That's just how it went. It just wasn't 22 a reagent that pharmaceutical chemists use. I 23 think the raw material suppliers that supply our 24 materials may use it, but we don't use it very 25 much.</p>	<p style="text-align: right;">Page 80</p> <p>1 Q. And you see where the FDA pointed out 2 that ZHP was required to ensure that unanticipated 3 impurities were appropriately detected and 4 controlled. Do you see that statement? 5 MS. ROSE: I'm sorry, are you reading 6 from the document, Adam? 7 MR. SLATER: Yes. 8 THE WITNESS: Show unanticipated were 9 probably detected. Yeah, I see that statement. 10 BY MR. SLATER: 11 Q. Your -- I think -- you can tell me if 12 this is outside the scope of your opinion -- but 13 you're not disagreeing with the FDA that ZHP was 14 required to ensure that unanticipated impurities 15 were appropriately detected and controlled? You 16 don't disagree with that; right? 17 MS. ROSE: Object to the form. 18 THE WITNESS: I don't see how you can 19 possibly do that. If you're not anticipating it 20 and you don't know what you're looking for, how 21 could -- how could you logically develop a method? 22 BY MR. SLATER: 23 Q. Let's go to the next sentence. The FDA 24 said, "You are responsible for developing and using 25 suitable methods to detect impurities when</p>
<p style="text-align: right;">Page 79</p> <p>1 Q. Why not? Why not use sodium nitrite? 2 A. Because the kind of chemistry we do, it 3 doesn't call for the use of -- of sodium nitrite. 4 It's just not -- it's not -- we don't need it for 5 the synthesis. 6 Q. So that wasn't something that you had 7 experience with in your active work; correct? 8 A. That wasn't something that I had what? I 9 could probably turn the sound up a little bit. 10 Q. That's okay. So you did not have 11 experience with the use of sodium nitrite in the 12 processes that you worked with; correct? 13 A. That's correct. 14 Q. Just as a basic chemistry -- I'll come 15 back to that. Let's go back to the warning letter, 16 okay? 17 A. Okay. 18 Q. Second paragraph under heading number two 19 says, "You also failed to evaluate the need for 20 additional analytical methods to ensure that 21 unanticipated impurities were appropriately 22 detected and controlled in your valsartan API 23 before you approved the process change." Do you 24 see what I just read? 25 A. Yes.</p>	<p style="text-align: right;">Page 81</p> <p>1 developing and making changes to your manufacturing 2 processes." I want to stop there. 3 You see, that's the FDA's view is that 4 that was required. You can see the FDA says that; 5 right? 6 A. Yes. 7 Q. Is that outside the scope of your opinion 8 in terms of whether that was required and how that 9 applied to ZHP? 10 A. You know, when I read that, I -- I -- I 11 read that as they had methods in place and they 12 were using them to detect impurities. So I don't 13 know -- I just don't know how you can expect them 14 to come up with a method to detect something they 15 don't know is there. I just don't know how that's 16 practical -- how that's practical guidance. 17 Q. You're not offering opinions in terms of 18 the risk assessment? You already told me that; 19 right? 20 A. Yes. 21 Q. Do you have an opinion or is it outside 22 the scope of your expertise as to whether the FDA 23 is correct that ZHP was responsible for developing 24 and using suitable methods to detect impurities 25 when developing and making changes to their</p>



<p style="text-align: right;">Page 82</p> <p>1 manufacturing processes?</p> <p>2 A. It's outside of my scope. But my opinion</p> <p>3 is they were responsible, and they did it.</p> <p>4 Q. Well, you told me you don't know what</p> <p>5 they did, actually; right?</p> <p>6 A. Well, I know they used the methods from</p> <p>7 the monograph. What's that called, the US -- I</p> <p>8 know they did -- they had a method from the USP</p> <p>9 monograph. And they used it to detect impurities.</p> <p>10 Q. Did you read --</p> <p>11 A. I know they -- sorry. I know they did</p> <p>12 that much.</p> <p>13 Q. Did you read the USP monograph?</p> <p>14 A. No, I didn't.</p> <p>15 Q. You don't have an opinion as to whether</p> <p>16 or not they complied with the USP; correct?</p> <p>17 MS. ROSE: Object to the form.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. That's outside the scope of your opinion;</p> <p>20 correct?</p> <p>21 A. You know, I have an -- I think they</p> <p>22 followed the USP, but I don't -- didn't look at it.</p> <p>23 I don't know exactly what they did. I think they</p> <p>24 were following USP.</p> <p>25 Q. Do you know what the USP required where</p>	<p style="text-align: right;">Page 84</p> <p>1 would -- you know, you might have got them,</p> <p>2 but -- okay, let's just say it was -- as conducted,</p> <p>3 it was not capable. Yes, actually, I don't think</p> <p>4 it was capable. I don't think --</p> <p>5 Q. -- quenching; right?</p> <p>6 A. Say that --</p> <p>7 Q. -- process did not use sodium nitrite --</p> <p>8 A. No, it did not. It did not. So it was</p> <p>9 not capable of performing nitrosamines.</p> <p>10 Q. It was not capable of producing</p> <p>11 nitrosamines; correct?</p> <p>12 A. Correct, unless you added that in.</p> <p>13 Q. And then ZHP added sodium nitrite to the</p> <p>14 next processes that they developed, including the</p> <p>15 zinc chloride process; right?</p> <p>16 A. That --</p> <p>17 MS. ROSE: Object to the form.</p> <p>18 THE WITNESS: That's correct.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. That was a change to the manufacturing</p> <p>21 process; right?</p> <p>22 A. Yes.</p> <p>23 Q. And the addition of DMF was another</p> <p>24 change to the manufacturing process that was added</p> <p>25 to the zinc chloride process; right?</p>
<p style="text-align: right;">Page 83</p> <p>1 ZHP changed the manufacturing process in terms of</p> <p>2 what ZHP was required to do at that point to test</p> <p>3 for potential impurities? Do you know what the USP</p> <p>4 required?</p> <p>5 A. No.</p> <p>6 MS. ROSE: Object to form.</p> <p>7 THE WITNESS: Oh. Sorry. No, I do not.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. So you don't know what standard would</p> <p>10 apply; correct?</p> <p>11 A. That's correct.</p> <p>12 Q. Do you understand what the chronology was</p> <p>13 of the various manufacturing processes that were</p> <p>14 used by ZHP to manufacture valsartan API were?</p> <p>15 A. Do I understand the chronology?</p> <p>16 Q. Yeah. Do you understand that there were</p> <p>17 several processes that were used in iteration?</p> <p>18 A. Yes.</p> <p>19 Q. Do you understand that the first process</p> <p>20 was called the tribunal team process?</p> <p>21 A. Yes.</p> <p>22 Q. Do you understand that process was not</p> <p>23 capable of creating nitrosamines?</p> <p>24 A. I wouldn't say it was not capable. If</p> <p>25 you use sodium nitrite in the quench, you</p>	<p style="text-align: right;">Page 85</p> <p>1 A. Yes.</p> <p>2 Q. And you can see that the FDA in the</p> <p>3 second paragraph, under heading number two, talks</p> <p>4 about what the obligations of ZHP were when they</p> <p>5 made changes to the manufacturing process. That's</p> <p>6 what they're talking about there; right?</p> <p>7 A. Yes.</p> <p>8 Q. And in terms of what ZHP was expected to</p> <p>9 do in order to try to anticipate potential</p> <p>10 impurities, you're not in a position to tell us</p> <p>11 what they were expected to do or what standards</p> <p>12 applied; right?</p> <p>13 MS. ROSE: Object to the form. Outside</p> <p>14 the scope.</p> <p>15 THE WITNESS: Yeah, I can't really tell</p> <p>16 what they were expected. I don't really know</p> <p>17 the -- the regulatory requirements.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. For example, you don't know what the</p> <p>20 regulatory requirements were for the level of</p> <p>21 scientific analysis ZHP was expected and required</p> <p>22 to perform in this context? You don't know that</p> <p>23 and you didn't apply that; correct?</p> <p>24 A. Yeah, that's correct.</p> <p>25 Q. Looking at this second paragraph, the</p>

<p style="text-align: right;">Page 86</p> <p>1 last sentence of this second paragraph says, "If 2 new or higher levels of impurities are detected, 3 you should fully evaluate the impurities and take 4 action to ensure the drug is safe for patients." 5 Do you agree with that statement, or is that 6 outside the scope of your opinion? 7 A. I agree with that -- that statement, but 8 it is outside the scope. 9 Q. Let's look at the third paragraph. The 10 FDA says, in the third paragraph here on page 4, 11 "Your response states that predicting NDMA 12 formation during the valsartan manufacturing 13 process required an extra dimension over current 14 industry practice, and that your process 15 development study was adequate. We disagree. 16 "We remind you that common industry 17 practice may not always be consistent with CGMP 18 requirements, and that you are responsible for the 19 quality of drugs you produce." 20 Do you see what I just read? 21 A. Yes. 22 Q. In your report you referred to industry 23 practice several times; right? 24 A. Yes. 25 Q. And when you talked about industry</p>	<p style="text-align: right;">Page 88</p> <p>1 complied with. 2 BY MR. SLATER: 3 Q. Based on your knowledge? 4 A. Based on -- yeah, based on common sense. 5 How can you -- how -- what are you supposed to 6 do -- what -- there's no reference to any 7 guidelines that you should follow that will help 8 you determine unanticipated unknowns. There's 9 no -- there's no reference to anything like that. 10 Q. If ZHP could have known that the DMF 11 could introduce dimethylamine either as an impurity 12 of the DMF and/or as a degradation product of the 13 DMF in the process, then you would agree ZHP had to 14 take that into account; right? 15 MS. ROSE: Object to the form. Improper 16 hypothetical. 17 THE WITNESS: So the introduction of 18 dimethylamine is not the same as the introduction 19 of NDMA. So you have to -- when he talks about 20 extra dimension here, there's actually two 21 dimensions, right? You have to recognize -- and 22 dimethylamine is going to form, and then you have 23 to recognize dimethylamine is going to react with 24 sodium nitrite to form NDMA. You have to recognize 25 those two things. So recognizing one alone is not</p>
<p style="text-align: right;">Page 87</p> <p>1 practice, you were basing that on your own 2 experience and the work that you did in your own 3 labs; correct? 4 MS. ROSE: Object to the form. 5 THE WITNESS: Yes. 6 BY MR. SLATER: 7 Q. You didn't do a study or analysis of what 8 other people were doing or what was being done 9 across the industry, you based it on your own 10 experience in your own work; correct? 11 A. Yes. 12 Q. Now, seeing that the FDA disagreed that 13 pointing to current industry practice is adequate 14 as a defense due to the failure to do this type of 15 analysis, do you agree or disagree with the FDA, or 16 is that outside the scope of your opinion? 17 MS. ROSE: Object to the form. 18 THE WITNESS: It's outside the scope. 19 But again, as I said before, I don't see how you 20 could practically comply with that. We remind you 21 that common industry practice may not always be 22 consistent with the GMP requirements. So then 23 what -- what are you supposed to do? There's no 24 guidance there as to what you are supposed to do. 25 So it's -- it's a statement that really can't be</p>	<p style="text-align: right;">Page 89</p> <p>1 enough to raise a red flag. 2 And I know in the depositions and 3 the reports, you know, the red flag goes up, the 4 alarm bells are going off, NDMA is forming, NDMA is 5 forming. That's not true. That is simply not 6 true. And I gotta take a bathroom break 7 after -- after saying that. I'll be right back. 8 MR. SLATER: Go ahead. We'll wait here 9 for you. We'll go off for a second and be right 10 here. 11 THE VIDEOGRAPHER: We're off the record 12 at 11:57 a.m. 13 (Break taken.) 14 THE VIDEOGRAPHER: We're back on the 15 record at 12:05 p.m. 16 BY MR. SLATER: 17 Q. We were talking about dimethylamine. So 18 I want to ask you a few questions about that, okay? 19 A. Sure. 20 Q. Do you know what dimethylamine is? 21 A. I know the chemical structure of it, yes. 22 I know what it is. 23 Q. What is it? Just how would you describe 24 it? 25 A. I would describe it as ammonia with two</p>

<p style="text-align: right;">Page 90</p> <p>1 methyl groups on it.</p> <p>2 Q. It's known as a secondary amine?</p> <p>3 A. It's a secondary amine, yes.</p> <p>4 Q. Did you learn -- when did you first learn</p> <p>5 what DMA was?</p> <p>6 A. I've probably -- it's not -- it's not a</p> <p>7 commonly used reagent, okay? It boils at</p> <p>8 seven -- it boils below room temperature. So you</p> <p>9 don't really use it for much. But dimethylamine,</p> <p>10 you know, people use. So I've known about it</p> <p>11 probably since undergrad. You know, over 50 years.</p> <p>12 Q. I think you said before -- you can</p> <p>13 correct me if I'm wrong -- that when you worked</p> <p>14 with DMF, you would have been aware that DMA can be</p> <p>15 an impurity of DMF. It's actually one of the two</p> <p>16 primary impurities of DMF; correct?</p> <p>17 MS. ROSE: Object to the form.</p> <p>18 THE WITNESS: Yeah, that's not exactly</p> <p>19 what I said. I mean, you asked me if that would be</p> <p>20 a contaminant.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. That's not what I asked, but --</p> <p>23 A. What did you --</p> <p>24 Q. I'm not trying to cut you off, but this</p> <p>25 is what I asked you.</p>	<p style="text-align: right;">Page 92</p> <p>1 process. You at least would have needed to know</p> <p>2 that to take it into account; correct?</p> <p>3 MS. ROSE: Object to the form, and</p> <p>4 misstates the testimony.</p> <p>5 THE WITNESS: So unless I saw a peak, a</p> <p>6 peak on a chromatogram to rise from dimethylamine</p> <p>7 interacting with my substrate, I would never -- I</p> <p>8 would never think about it as being a problem. I</p> <p>9 have to see a peak to flag me. It's called</p> <p>10 a -- what would I call that? Instigation. Or it's</p> <p>11 a -- you just -- I have to see a peak. That's the</p> <p>12 triggering event, okay? That's the word. I see a</p> <p>13 peak, it's my triggering event. If I don't see a</p> <p>14 peak, I'm not thinking about it.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. In the entire time you worked with DMF,</p> <p>17 though, you were aware -- I think you said this</p> <p>18 earlier -- that DMA was a potential impurity or</p> <p>19 degradant of the DMF? You at least told me you</p> <p>20 were aware of that; correct?</p> <p>21 MS. ROSE: Object to the form. Misstates</p> <p>22 testimony.</p> <p>23 THE WITNESS: I might have -- I might</p> <p>24 have heard of it and I -- I forgot about it. I</p> <p>25 mean, it's one of those factoids, it just</p>
<p style="text-align: right;">Page 91</p> <p>1 A. Okay. Yeah, let me -- let me -- I need</p> <p>2 to hear that again. Sorry.</p> <p>3 Q. Would you -- and I'll try to ask it the</p> <p>4 same way I asked it before, but I'm going to add in</p> <p>5 the information you gave me in the answer so I can</p> <p>6 make it more correct.</p> <p>7 A. Okay. That's fine.</p> <p>8 Q. You mentioned formic acid when I asked</p> <p>9 the question.</p> <p>10 Would you agree with me that the two</p> <p>11 primary DMF impurities/degradants are dimethylamine</p> <p>12 and formic acid?</p> <p>13 MS. ROSE: Object to the form.</p> <p>14 THE WITNESS: Yes. I mean, I've</p> <p>15 done -- I'm looking at this now for six weeks, so,</p> <p>16 yeah, I know that. And if you're sitting there</p> <p>17 having a discussion with me at the coffee table, I</p> <p>18 would say that. But I would never pick up a bottle</p> <p>19 of DMF and think those things are in there.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. You agree with me, 'cause you talked to</p> <p>22 me about the importance of being aware of potential</p> <p>23 impurities, that when you worked with DMF, you were</p> <p>24 at least aware that that could potentially</p> <p>25 introduce dimethylamine into the manufacturing</p>	<p style="text-align: right;">Page 93</p> <p>1 doesn't -- doesn't stay unless it's continuously</p> <p>2 reinforced.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. Am I correct that when you used DMF, you</p> <p>5 never did any independent research into the</p> <p>6 potential impurities or degradants of DMF?</p> <p>7 A. No. If I used it and it worked in my</p> <p>8 reaction, I didn't look at the degradants. But you</p> <p>9 also have to be aware that everything that people</p> <p>10 use is less than a hundred percent pure. Every</p> <p>11 single agent is less than a hundred percent pure,</p> <p>12 and every single reaction doesn't give exactly one</p> <p>13 thing. So that's just common everyday occurrence.</p> <p>14 Q. You would agree with me that anybody</p> <p>15 working at ZHP should have been aware of what you</p> <p>16 just said; right?</p> <p>17 MS. ROSE: Object to the form.</p> <p>18 THE WITNESS: Yeah, I think chemists -- I</p> <p>19 think chemists generally know their materials are</p> <p>20 not a hundred percent pure and their reactions</p> <p>21 don't go to a 100.0 percent either.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. If ZHP was aware of the potential that</p> <p>24 the DMF could introduce dimethylamine into the zinc</p> <p>25 chloride process, do you have any opinions as to</p>

24 (Pages 90 - 93)

<p style="text-align: right;">Page 94</p> <p>1 what they needed to do in response to that, or is 2 that outside the scope of your opinion? 3 MS. ROSE: Object to the form. Improper 4 hypothetical. 5 THE WITNESS: That's outside the scope. 6 BY MR. SLATER: 7 Q. And it would be the same answer if I were 8 to add into my hypothetical that ZHP, in the event 9 they knew that dimethylamine could potentially be 10 introduced to the process, either as an impurity or 11 as a degradant of the DMF, and that they were using 12 that in a process where it would be exposed to 13 sodium nitrite or nitrous acid, what they needed to 14 do in response to that, the answer would be the 15 same, I assume, that's outside the scope of your 16 opinion in terms of what they needed to do with 17 that information? 18 MS. ROSE: Object to the form. 19 THE WITNESS: Yeah. I mean, I guess 20 that's outside -- yeah, it's outside the scope. 21 BY MR. SLATER: 22 Q. Did you see literature among the 23 materials you were provided by counsel indicating 24 whether there was knowledge in the chemistry 25 community that the combination of dimethylamine and</p>	<p style="text-align: right;">Page 96</p> <p>1 A. If they had a reason to search for it, 2 they -- it was available. Yes, it was -- it's 3 published with dates and page numbers. Yes, it was 4 available if you wanted to find it. If you -- if 5 you were looking for it. 6 Q. If you were looking for information about 7 dimethylamine and how it might react with sodium 8 nitrite, that information was available; correct? 9 A. If you wanted to find it, yes. 10 Q. And if you wanted to find information 11 about what are the potential impurities that could 12 be introduced by using DMF, you agree that 13 information was available if somebody looked for 14 it; correct? 15 MS. ROSE: Object to the form. 16 THE WITNESS: Yes. 17 BY MR. SLATER: 18 Q. And that would include that if somebody 19 wanted to research that issue of what -- rephrase. 20 If somebody actually did research one 21 of the potential impurities that could have been 22 introduced into the manufacturing process when we 23 use DMF, you would agree that if somebody wanted to 24 look at that question, that they could have learned 25 that one of those impurities that could have been</p>
<p style="text-align: right;">Page 95</p> <p>1 sodium nitrite could create NDMA? Did you see any 2 literature in the materials you reviewed indicating 3 that? 4 A. Yes. 5 Q. For example, did you see in the IARC 6 monograph on the evaluation of the carcinogenic 7 risk of chemicals to humans from the 1970s that the 8 IARC monograph indicated, "it has been known since 9 1865 that the reaction of dimethylamine 10 hydrochloride with sodium nitrite at an acidic PH 11 is in nitrosamine dimethylamine." Did you see 12 that? 13 A. Yes, I did. 14 Q. And you would agree that the people at 15 ZHP would have been expected to know that; correct? 16 A. No. 17 Q. And again, you're not able to tell us 18 what, from a regulatory standpoint, ZHP's people 19 were supposed to do to evaluate the potential 20 reactions in the process? That's not something 21 you're giving opinions on; right? 22 A. I'm not giving opinions on that. 23 Q. Do you agree with me that the information 24 I just read to you was available to scientists in 25 2011 if they wanted to consult it?</p>	<p style="text-align: right;">Page 97</p> <p>1 introduced was dimethylamine? That was available 2 information in the literature; correct? 3 MS. ROSE: Object to the form. Improper 4 hypothetical. 5 THE WITNESS: Yes, it was available. 6 BY MR. SLATER: 7 Q. You agree with me that if ZHP wanted to 8 evaluate -- rephrase. 9 Are you aware of when ZHP got 10 any -- any notice from anybody, whether internal to 11 the company or outside the company, that there were 12 peaks for the valsartan API manufactured by the 13 zinc chloride process that were unidentified and of 14 concern? Do you know when ZHP first became aware 15 of that? 16 A. Yes. I saw that in the customer 17 complaints. And I can't remember if that was in 18 Najafi's report. I think it was. And I think the 19 first one was probably 2014, and then 2015, 2016. 20 Those are peaks in the GCFID trace, the residual 21 solvent trace, yes. 22 Q. I didn't see any discussion in your 23 report about what ZHP did or did not do with regard 24 to the peaks showing on chromatography. I didn't 25 see any opinions on that. Am I correct that's not</p>

<p style="text-align: right;">Page 98</p> <p>1 something you're opining on?</p> <p>2 MS. ROSE: Object to the form.</p> <p>3 THE WITNESS: No. But, I mean, I -- from</p> <p>4 the deposition testimony I kind of -- I kind of</p> <p>5 know what happened there.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. What I'm asking is -- you know what</p> <p>8 happened, but -- and I think you just</p> <p>9 confirmed -- you're not offering any opinions about</p> <p>10 what ZHP should or shouldn't have done in response</p> <p>11 to those peaks; right?</p> <p>12 MS. ROSE: Object to form.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. I didn't see any discussion of that in</p> <p>15 your report.</p> <p>16 A. I didn't put any discussion in my report,</p> <p>17 but they responded to those requests.</p> <p>18 Q. You're not offering any opinions about</p> <p>19 whether what they did was adequate or not? That's</p> <p>20 not something you've opined on; correct?</p> <p>21 MS. ROSE: Object to the form.</p> <p>22 THE WITNESS: No, I didn't put anything</p> <p>23 in my report. But I should -- I'll leave that one</p> <p>24 up to -- I mean, my understanding was the customers</p> <p>25 were satisfied with their response.</p>	<p style="text-align: right;">Page 100</p> <p>1 capabilities included an LCMS machine for mass</p> <p>2 spectrometry and Ajilent, A-J-I-L-E-N-T, 1100, and</p> <p>3 a GCMS Ajilent 7890A? Did you see that --</p> <p>4 A. No.</p> <p>5 Q. -- in the materials you reviewed?</p> <p>6 A. No.</p> <p>7 Q. You would agree with me that if ZHP</p> <p>8 wanted to utilize GCMS or LCMS going back to 2011,</p> <p>9 that technology was available and could have been</p> <p>10 used by them; correct?</p> <p>11 MS. ROSE: Object to the form.</p> <p>12 THE WITNESS: Yes, it was available. But</p> <p>13 I remember from the Hecht deposition the question</p> <p>14 came up of how many USP monographs there are and</p> <p>15 how many compounds in that monograph use GCMS as a</p> <p>16 tool for residual solvent analysis, and it was</p> <p>17 something like four -- four compounds in the</p> <p>18 monograph out of 5,000 actually used GCMS. It's a</p> <p>19 very rarely used tool for residual solvents,</p> <p>20 especially in that timeframe.</p> <p>21 So it's unreasonable to expect</p> <p>22 somebody to use a tool that's used one in a</p> <p>23 thousand times to pull that off the shelf and let's</p> <p>24 try it here and see what happens. That's just</p> <p>25 a -- not a likely or plausible scenario.</p>
<p style="text-align: right;">Page 99</p> <p>1 BY MR. SLATER:</p> <p>2 Q. But just to be clear, that's not</p> <p>3 something you offered any opinions on in your</p> <p>4 report about whether ZHP did an adequate evaluation</p> <p>5 of those unidentified peaks or not? That's not</p> <p>6 something that's addressed in your report at all;</p> <p>7 correct?</p> <p>8 A. Yeah, that's not in my report.</p> <p>9 Q. You do agree with me that GCMS and LCMS</p> <p>10 technology was available to ZHP throughout the time</p> <p>11 that they were manufacturing and selling the</p> <p>12 valsartan API; correct?</p> <p>13 A. So from Min Li's deposition, I got it</p> <p>14 that the first LCMS was purchased at ZHP in 2013.</p> <p>15 So I don't think it was available while they were</p> <p>16 doing the process work.</p> <p>17 Q. We have a PowerPoint which I can show</p> <p>18 you.</p> <p>19 MR. SLATER: Can we pull it up, Chris?</p> <p>20 You know which one I'm talking about? All right.</p> <p>21 We'll come back to it then.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. Let me ask you if you've seen this. Have</p> <p>24 you seen a PowerPoint from ZHP dated August 23,</p> <p>25 2012 indicating that their research and development</p>	<p style="text-align: right;">Page 101</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Are you aware that before June 2018, ZHP</p> <p>3 was using GCMS and LCMS technology to evaluate</p> <p>4 impurities in their drug substance?</p> <p>5 MS. ROSE: Object to the form.</p> <p>6 THE WITNESS: You know, yeah, I guess</p> <p>7 from reading Min Li's deposition, that CEMAT --</p> <p>8 CEMAT group that he built, I believe he bought --</p> <p>9 he bought those instruments to look at -- to look</p> <p>10 at impurities in the new products they were</p> <p>11 developing, not going back retrospectively to look</p> <p>12 at existing products.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. The technology was available for whatever</p> <p>15 purpose somebody wanted to use it for; correct?</p> <p>16 MS. ROSE: Object to form.</p> <p>17 THE WITNESS: Yes.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. And you're aware that one of the uses for</p> <p>20 a GCMS machine is if you see a peak on regular gas</p> <p>21 chromatography and you can't identify it, GCMS</p> <p>22 technology can be used to actually identify what</p> <p>23 that peak is? That's one of the common uses of</p> <p>24 GCMS technology; right?</p> <p>25 A. Right. But things that are below the</p>



<p style="text-align: right;">Page 102</p> <p>1 reporting threshold you're not going to focus on.  2 Those are going to be below the level at which you  3 work on them. And below the -- the identification  4 threshold would be a thousand PPM. So you would  5 use GCMS if something was below -- above a thousand  6 PPM, but you're -- you know, below 500 PPM, you  7 don't have to report that.  8 Q. Are you aware of the regulatory standards  9 that indicated that certain genotoxic impurities  10 were of such concern due to their toxicity that the  11 threshold did not apply to them?  12 MS. ROSE: Object to the form.  13 BY MR. SLATER:  14 Q. Yes or no, were you aware of that?  15 A. So the issue there is you have to know a  16 peak is a genotoxic impurity. It's kind of a  17 catch-22. So if you don't -- if it's below 500 PPM  18 and you don't know it's a genotoxic impurity,  19 you're not going to identify it. You have to know  20 it's -- so you -- if you're using a genotoxic  21 impurity and you see it there, and -- so this is  22 what the guidance actually says. If you see a  23 genotoxic impurity and you're looking for it, you  24 see it, it's 50 PPM, you have to report that. But  25 there is a gap in the guidance for things below 500</p>	<p style="text-align: right;">Page 104</p> <p>1 MS. ROSE: Object to the form.  2 BY MR. SLATER:  3 Q. Let me ask the question differently.  4 Withdraw the question.  5 This area in terms of what they needed  6 to look for, is this outside the scope of your  7 opinion?  8 A. Yes, it is.  9 Q. Okay. In terms of whether or how they  10 should have used the technology, that's not  11 something you're opining on, but you'll agree with  12 me the technology, GCMS and LCMS, was available to  13 ZHP if it wanted to use that technology from 2011  14 all the way through? You'll agree with me on that  15 statement; correct?  16 A. According to the PowerPoint, they had  17 those instruments -- they're saying they had those  18 instruments sometime in 2012. So from that point  19 on, yes, they had them there.  20 Q. And the technology was available even  21 before that if they chose to obtain it or get  22 access to it whether they owned it themselves or  23 not; right?  24 MS. ROSE: Object to the form.  25 THE WITNESS: Yes, the technology was</p>
<p style="text-align: right;">Page 103</p> <p>1 PPM and above the level of detection.  2 Q. Are you telling me there's a guidance you  3 can point to that says that if a cohort of concern  4 substance, for example, an N-nitroso compound, has  5 a peak, but you don't know that the peak is for the  6 nitrosamine, you don't have to try to figure out  7 what that peak is for?  8 A. No, that's not --  9 Q. -- ignore it because it's small?  10 MS. ROSE: Object to the form.  11 BY MR. SLATER:  12 Q. Is that your testimony?  13 A. That is not my testimony.  14 Q. Okay. That's what I was asking.  15 MS. ROSE: Can I just --  16 MR. SLATER: Wait.  17 MS. ROSE: Dr. Thompson, please let  18 Mr. Slater finish his question before you give your  19 answer, and also allow me time to object so we can  20 spare the court reporter, please.  21 THE WITNESS: All right.  22 BY MR. SLATER:  23 Q. You're not suggesting that you need to  24 know the answer before you start to look for the  25 answer; right?</p>	<p style="text-align: right;">Page 105</p> <p>1 available if you -- if you saw a need to use it.  2 MR. SLATER: Why don't we -- I think this  3 is a good time. You said you wanted to break  4 around 12:30, and I think we're pretty much there,  5 rather than me jumping into another document. So  6 let's go off.  7 THE VIDEOGRAPHER: We're off the record  8 at 12:25 p.m.  9 (Break taken.)  10 THE VIDEOGRAPHER: We're back on the  11 record at 1:35 p.m.  12 BY MR. SLATER:  13 Q. Doctor, I want to ask you a couple  14 questions about a 2017 e-mail that you reference on  15 page 6 of your report.  16 A. Okay.  17 Q. Did you read that e-mail written by  18 Dr. Jinsheng Lin?  19 A. I read the translation.  20 Q. You state in your report, "It is  21 difficult to interpret this e-mail." Why did you  22 say that?  23 A. Yeah. I mean, so the e-mail, the body  24 text and the patent that he references, is really  25 about nitrosations of a sartan background -- of</p>

<p style="text-align: right;">Page 106</p> <p>1 nitrogen and a sartan background. So it's really 2 about nitrosations of the API or the deacylated 3 API. So that's the whole topic. That's the 4 attachment. 5 And then out of the blue comes this 6 sentence, you know, similar to the NDMA found in 7 valsartan. It's kind of a non -- it's a non 8 sequitur. So, I mean, quite honestly, I thought it 9 was poorly interpreted. I just thought my 10 interpretation was wrong, and that those words 11 weren't right -- weren't a perfect interpretation 12 of what was written in the e-mail. 13 And, you know, I don't have much of a 14 basis for saying that. It's just that it's -- it's 15 just a non sequitur. There's no backup data in 16 addition to that one sentence. So I had a little 17 difficulty with it. 18 And then I guess I finally decided 19 that the interpretation that probably fits all the 20 data is that he's trying to, you know, calibrate 21 this team. This is how important I see this issue 22 for the company. So it's similar to a situation 23 where we have NMDA in valsartan. You know, 24 that's -- that's where I put this issue in terms of 25 importance for things you should think about.</p>	<p style="text-align: right;">Page 108</p> <p>1 were uniformly the company didn't know. That's 2 not -- that's not what he said. The company didn't 3 know. Uniformly, every time he was asked a 4 question about that e-mail, that's what his 5 response was. Every time. That's what I remember 6 his response being. Yeah. 7 BY MR. SLATER: 8 Q. You don't recall in the deposition of Min 9 Li when I walked through with him the entire e-mail 10 and what it said? 11 A. So, you know, I can't -- I don't recall 12 every word that was said, but my general impression 13 of what he said -- I looked back at it recently, a 14 day or two ago, and generally what he was saying is 15 the company did not know. Every time he was asked 16 the company knew, and his response was the company 17 did not know. It was this one guy who had a 18 theory. 19 Q. Do you know what Jinsheng's -- I'm sorry. 20 Do you know what Jinsheng Lin's job was? 21 A. Again, I'm going to assume what it was. 22 First of all -- 23 Q. I'm asking if you know what his job was. 24 A. No, I do not. Oh, yes, he was -- he 25 worked in the CEMAT group. He did something in the</p>
<p style="text-align: right;">Page 107</p> <p>1 So, you know, that's kind of the basis 2 for that statement it's difficult to interpret. 3 Q. You know, I assume you don't read or 4 write the Chinese language; is that correct? 5 A. I do not. I don't even take Chinese 6 cash. 7 Q. Did you read -- you mentioned 8 that -- rephrase. 9 You mentioned that you read two of the 10 days of Min Li's deposition. Do you recall if you 11 read the day where he was asked about this e-mail? 12 A. Yeah, I did. 13 Q. Do you know who Min Li is? 14 A. I don't know exactly his position at the 15 company. He's like a director of -- I think he's 16 the guy -- the top man in charge of the analytical 17 department at ZHP. That's what I think his job is. 18 Q. Do you understand that he actually is the 19 person that Jinsheng Lin reported to? 20 A. Yes. 21 Q. And did you see that we asked Min Li 22 about the e-mail and he testified to what the 23 e-mail said? 24 MS. ROSE: Object to the form. 25 THE WITNESS: Yeah, Min Li's responses</p>	<p style="text-align: right;">Page 109</p> <p>1 CEMAT group. 2 Q. Do you know what he did in the CEMAT 3 group? 4 A. Not exactly. Seemed like a bunch of 5 things. 6 Q. Do you know that he was in charge of the 7 group that was responsible to identify the root 8 causes of impurities seen in drug substance? 9 MS. ROSE: Object to the form. 10 THE WITNESS: I assumed he was in that 11 group, yeah, that identified impurities, yeah. 12 BY MR. SLATER: 13 Q. And you understand that Min Li was the 14 head of CEMAT; right? 15 A. Yes. 16 Q. Do you recall Min Li saying that he 17 doesn't recall seeing the e-mail because he gets a 18 lot of e-mails and he doesn't recall seeing it? 19 A. That's right, he did -- he did say that. 20 So then all -- 21 Q. I'm just asking if you remember him 22 saying that. 23 A. Huh? 24 Q. I'm just asking if you remember him 25 saying that.</p>



<p style="text-align: right;">Page 110</p> <p>1 A. Now that you bring it up, yes, I do 2 remember that, yes. 3 Q. Do you remember him confirming that as 4 part of the e-mail, the e-mail states that what was 5 being seen in its irbesartan product they were 6 working with is similar to the NDMA that occurs in 7 valsartan when quenched with sodium nitrite? 8 MS. ROSE: Object to the form. Are you 9 reading from a document? 10 MR. SLATER: I'm reading from the 11 translation that is cited in the reliance list by 12 your expert, by Dr. Thompson. 13 MS. ROSE: Okay. You're asking -- 14 MR. SLATER: The question -- 15 MS. ROSE: -- something he's not looking 16 at? 17 MR. SLATER: I'm not sure why that's 18 funny, but I'll continue. I'll ask a new question. 19 MS. ROSE: I wasn't -- 20 MR. SLATER: Let's -- 21 MS. ROSE: -- addressing anything as 22 funny. 23 BY MR. SLATER: 24 Q. Let me ask you this, Doctor. New 25 question.</p>	<p style="text-align: right;">Page 112</p> <p>1 I just don't recall it. 2 BY MR. SLATER: 3 Q. We're going to put up as the next 4 exhibit -- what are we up to, six, now? Exhibit 6 5 is going to be the e-mail, which is ZHP00190573, 6 which is listed in your list of materials reviewed 7 as one of the documents that you reviewed. 8 A. Okay. 9 MS. ROSE: Is this Exhibit 7? 10 MR. SLATER: This is I think six, I was 11 told by Chris. 12 MS. ROSE: Oh, apologies. 13 MR. SLATER: I mean, we'll stand to be 14 corrected if it's seven, but... 15 MS. ROSE: No, it's fine. I have six. I 16 thought seven -- I thought there was a seven that 17 hadn't popped up yet. But I've got it at six. 18 Okay, I got it. 19 BY MR. SLATER: 20 Q. First of all, you've read this; right? 21 A. Yes. 22 Q. Let's look -- looking at the first page 23 of the document -- let's go scroll -- perfect. 24 In the first -- first paragraph you 25 can see it's written to someone saying -- someone</p>
<p style="text-align: right;">Page 111</p> <p>1 Do you remember Min Li testified to 2 what the e-mail said? 3 MS. ROSE: Object to the form. 4 BY MR. SLATER: 5 Q. Do you remember -- I'll ask it 6 differently. 7 Do you remember Min Li having the 8 Chinese language version of the e-mail in front of 9 him, and walking through the e-mail and testifying 10 to what it said? Do you recall that happening in 11 his deposition? 12 A. I remember reading that in the 13 deposition. I don't remember every word of every 14 response, but I remember that he was walking 15 through it. 16 Q. And do you recall that as part of that he 17 agreed that the e-mail said words to the effect of 18 that what was being seen in this irbesartan 19 substance they were working with was similar to the 20 NDMA that occurs in valsartan as a result of the 21 sodium nitrite quenching? Do you recall that was 22 part of what he said the e-mail stated? 23 MS. ROSE: Object to the form. 24 THE WITNESS: I don't exactly recall. I 25 don't exactly recall that. He might have said it.</p>	<p style="text-align: right;">Page 113</p> <p>1 named Jucai Ge. Do you see that? 2 A. Yes. 3 Q. Do you know who that is? 4 A. So I didn't know -- you know, when I 5 wrote the report, I didn't know. But then when I 6 read the deposition, I could see Min Li describing 7 who all these people were and what their job titles 8 were. 9 Q. It's people -- 10 A. So I -- 11 Q. -- pretty high level people in the 12 company; right? 13 A. Yeah. That's why I thought it was kind 14 of strange that he was writing a chemistry e-mail 15 to all these executives with all this chemistry, 16 mass specs and reaction mechanisms, to all these 17 high level people, and none of them are chemists. 18 I was like, that's a little odd. You know, I 19 could -- I don't know if any of them actually read 20 it. But I looked at it and said this is not in my 21 wheelhouse and closed it. That's -- that's what I 22 thought. 23 Q. You thought none of these people were 24 chemists? 25 MS. ROSE: Object to the form.</p>

<p style="text-align: right;">Page 114</p> <p>1 THE WITNESS: I was -- I was -- I didn't 2 know all eleven of them or how many of them. But 3 there was a QA person. There was a regulatory 4 affairs person that Min pointed out. There was 5 analytical people. It didn't mention the name of 6 one single chemist, synthetic chemist in process 7 chemistry on that list. 8 It might have been 'cause I didn't 9 read every one, but I was surprised at their job 10 functions in relation to what this e-mail was 11 about. I was -- why would he send to those people. 12 But, okay. 13 BY MR. SLATER: 14 Q. Do you know what Min Li's background is? 15 A. Min Li? 16 Q. Yeah, Min Li. He's on the -- 17 A. Yeah, he's an -- he's an analytical 18 chemist. Johns Hopkins. Then he went to Schering. 19 Then he went to Merck. He went back to Schering. 20 I saw that because my wife worked at Schering, I 21 worked at Merck. And then Merck acquired Schering, 22 so he went back to Merck. Hey, got a pretty good 23 pedigree. Analytical chemistry. 24 Q. In the first paragraph of this e-mail, 25 the last sentence says, "However, after the</p>	<p style="text-align: right;">Page 116</p> <p>1 identified. You see an unknown peak. You figure 2 out what it is, and you work your way backwards to 3 how it happened. This is exactly an example 4 illustrating the process of impurity 5 identification. If you don't see a peak, you're 6 blind. He saw a peak. He figured out where it 7 was. He figured out where it came from. And he 8 figured out what to do with the process to fix 9 that. 10 BY MR. SLATER: 11 Q. So an unknown peak, right, didn't know 12 what it was at first, and then had to investigate 13 it; right? 14 A. Yeah, because he saw it. He saw it. It 15 was there on the chromatogram. The biggest peak as 16 well. It was -- it was -- that's the kind of thing 17 the FDA is saying in all their guidance. You see a 18 peak, you identify it. You don't ignore a peak. 19 That's what they're saying in their guidance, and 20 that's what they did. 21 Q. Coming back to the question I asked. I'm 22 just asking. He saw an unknown peak and 23 investigated it; correct? 24 A. Yes. 25 Q. And then let's go to page 2. At the very</p>
<p style="text-align: right;">Page 115</p> <p>1 improvement there is an unknown impurity of about 2 0.544 percent at 26 minutes in the crude 3 irbesartan, and is the largest impurity in the 4 irbesartan crude product." Do you see that? 5 A. Yes. 6 Q. And then the next paragraph, the third 7 line -- the second and third line, he says, "Based 8 on the test results of these two days, currently it 9 can be confirmed that the impurity is a nitroso 10 derivative of the irbesartan." Do you see that? 11 A. Yes. 12 Q. So certainly by July 2017 we have 13 documentation that ZHP was aware that in this 14 process for developing a sartan, a nitroso compound 15 was being produced? That's what this sounds, 16 right? 17 MS. ROSE: Object to the form. 18 THE WITNESS: This plays exactly into 19 how -- 20 BY MR. SLATER: 21 Q. I'm just asking if that's what it says, 22 sir. 23 MS. ROSE: Please let him explain his 24 answer. He's answering your question. 25 THE WITNESS: This is how impurities are</p>	<p style="text-align: right;">Page 117</p> <p>1 top, he says, "Through the secondary mass 2 spectrometry analysis, it can be inferred that the 3 extra NO substituent is in the cyclic compound 4 fragment, and it is very likely that it is an N-NO 5 compound." Do you see what I just read? 6 A. Yes. 7 Q. So first of all, we know that he 8 evaluated this unknown peak using mass 9 spectrometry; right? 10 A. He had a trigger to do that evaluation, 11 yes. 12 Q. I didn't ask you about a trigger, Doctor. 13 A. I answered your question. I said yes. 14 Q. Okay. Let me ask it again, and we'll 15 just -- what I'm going to ask of you, to the best 16 of your ability, is if you could try to answer just 17 the question I ask and not talk about something 18 else as well, 'cause I'll -- 'cause I'm going to 19 keep coming back and we'll just make it go faster. 20 And as I told everybody, I cut out a bunch of stuff 21 before to try to move it along, but if we start to 22 now go through other things when I ask a question, 23 I'm going to have to keep coming back. It'll take 24 longer. 25 MS. ROSE: Adam, please don't direct the</p>

<p style="text-align: right;">Page 118</p> <p>1 witness how to answer your question.  2 MR. SLATER: I think I was about to --  3 MS. ROSE: He's answering --  4 MR. SLATER: -- not interrupting, Nina.  5 So, please.  6 MS. ROSE: Well, please don't direct the  7 witness or suggest to the witness that he's not  8 answering your question. He is answering your  9 question.  10 MR. SLATER: Okay. So if I ask what  11 color the light was and somebody starts telling me  12 about how a car drove, and then at the end says  13 yeah, but the light was red, you think that's  14 responsive? You don't have to answer that. But  15 that's what just happened. And I would appreciate  16 if we don't have that happen all day.  17 MS. ROSE: Object to the  18 characterization.  19 MR. SLATER: I really will go to ten  20 o'clock if we're going to start this now.  21 THE WITNESS: Okay. I'll do my best.  22 MR. SLATER: Thank you. I appreciate it.  23 BY MR. SLATER:  24 Q. Looking at the top of page 2, one thing  25 we know is that this Dr. Lin in CEMAT in July of</p>	<p style="text-align: right;">Page 120</p> <p>1 I'm going to ask the question again.  2 MS. ROSE: Okay. Please don't badger the  3 witness, Adam.  4 MR. SLATER: I'm not badgering him. I  5 think I've been as polite as possible. And I'm not  6 going to ascribe any motives, but I'm just saying I  7 didn't ask if it was a quasi-ignorant statement,  8 so...  9 BY MR. SLATER:  10 Q. So let me ask it again. This says, in  11 the next sentence, "It is similar to the  12 N-nitrosodimethylamine that occurs in valsartan  13 when quenched with sodium nitrite, and its  14 structure is very toxic." That's what it says;  15 right?  16 A. Yes, that's what it says.  17 Q. And as was stated a moment ago,  18 N-nitrosodimethylamine is NDMA; correct?  19 A. Yes.  20 Q. He says that the NDMA occurs in  21 valsartan; right?  22 A. Yes.  23 Q. And he says it occurs in valsartan when  24 quenched with sodium nitrite; correct? That's what  25 the words on the page say; right?</p>
<p style="text-align: right;">Page 119</p> <p>1 2017 used mass spectrometry to identify an unknown  2 peak; correct?  3 MS. ROSE: Object to the form. Already  4 asked and answered.  5 BY MR. SLATER:  6 Q. That's what happened; correct?  7 A. Yes.  8 Q. And he concluded it's very likely it is  9 an N-NO compound, meaning a nitrosamine; correct?  10 A. Yes.  11 Q. He then states, "It is similar to the  12 N-nitrosodimethylamine" -- and that's NDMA; right?  13 A. Yes, it is.  14 Q. -- "that occurs in valsartan when  15 quenched with sodium nitrite, and its structure is  16 very toxic." That's what it states here; correct?  17 A. Yeah. I thought that was a  18 quasi-ignorant statement. But yes, that's what it  19 says.  20 Q. I have to ask the question again, 'cause  21 I didn't ask if it was a quasi-ignorant statement.  22 So now I have to ask it again, Doctor.  23 A. I'm going to have to go to the bathroom.  24 Q. I don't care. You can go to the bathroom  25 as much as you want. But every time you do that,</p>	<p style="text-align: right;">Page 121</p> <p>1 A. That's what the words on the page say.  2 Q. And you know, as you sit here right now,  3 that the NDMA that formed in the valsartan occurred  4 due to the sodium nitrite quenching. That's a  5 correct statement of the root cause; correct?  6 A. Yeah, I just -- it's just -- that  7 sentence is completely out of context with the rest  8 of the e-mail.  9 Q. My question is this: The statement that  10 the NDMA occurs in valsartan when quenched with  11 sodium nitrite is an accurate statement and  12 accurately states the root cause for the formation  13 of NDMA in valsartan. You know that as you sit  14 here right now; correct?  15 A. So --  16 MS. ROSE: Object to the form.  17 THE WITNESS: -- my first impression when  18 I read this was it was not -- the English --  19 whoever did the interpretation got it wrong. I  20 didn't believe those words. I see them there, but  21 I don't -- I didn't believe them.  22 BY MR. SLATER:  23 Q. So your opinion is that those words just  24 don't belong there and you can't explain where they  25 come from, so you just are negating them and</p>

<p style="text-align: right;">Page 122</p> <p>1 setting them aside and not taking them into account  2 in your opinion? That's a yes or no question.  3 MS. ROSE: Object to the form.  4 BY MR. SLATER:  5 Q. Do I understand you correctly?  6 A. I'm trying to get them to fit.  7 Q. Okay. Let me come back. The reason  8 you're having trouble getting them to fit is  9 because you can't believe that somebody at ZHP knew  10 that there was NDMA in valsartan and what the root  11 cause was in July of 2017, and nobody said anything  12 to the public about it? That's the problem you're  13 having with this, is how could they know this and  14 not tell anybody? That's the issue; right?  15 MS. ROSE: Object to the form.  16 THE WITNESS: The issue is it's out of  17 context and there's no backup data. There's no  18 data to support that. I respect data.  19 BY MR. SLATER:  20 Q. Did you ask the lawyers who retained you,  21 hey, what's the background behind this document?  22 Did you ask them that question?  23 A. We talked about it a little -- yes.  24 Q. Okay. Did you know or did you learn that  25 this document was produced to us as a PDF off of</p>	<p style="text-align: right;">Page 124</p> <p>1 in the metadata that all these other people got it?  2 MS. ROSE: Object to the form. Object to  3 the characterization. Object to discussions of  4 discovery issues.  5 MR. SLATER: Your objection is noted.  6 BY MR. SLATER:  7 Q. Can you answer the question, Doctor?  8 A. Yeah, no one told me that. I didn't ask.  9 Q. Okay. If -- all right. So let me come  10 back to what I actually was trying to ask you  11 before we went down this side road.  12 The statement that there's NDMA in  13 valsartan, and the root cause is the quenching with  14 sodium nitrite, is a true and accurate statement of  15 the root cause for the NDMA formation in the  16 valsartan. You know that as you sit here right  17 now; correct?  18 MS. ROSE: Object to the form.  19 THE WITNESS: That's what -- yeah, that's  20 what the deviation investigation says, and that's  21 the theory, yes.  22 BY MR. SLATER:  23 Q. And you agree with that; right?  24 A. Yes.  25 Q. So it's not just that he said there's</p>
<p style="text-align: right;">Page 123</p> <p>1 Min Li's laptop, and that nobody else who received  2 it was listed as a duplicate custodian, suggesting  3 that we were never supposed to see the document?  4 Were you aware of that?  5 MS. ROSE: Object to the form. Object to  6 the characterization.  7 BY MR. SLATER:  8 Q. I'm asking if you were aware of that,  9 that that's what we're asserting in this litigation  10 and have asserted in open court.  11 A. So I don't know what --  12 Q. Is that yes or no?  13 A. I don't know what a duplicate custodian  14 means. I don't know what that term means.  15 Q. Duplicate custodian means that every  16 single person that received this e-mail -- and we  17 talked about the long list before -- every one of  18 them, when it was produced to us, there's something  19 called metadata, and it's supposed to list every  20 person that got it so that we know, okay, we didn't  21 produce it ten times to you, but it went to all  22 these people and was in their files when the  23 documents were produced.  24 Did anybody ever tell you that, that  25 they were -- it actually was never disclosed to us</p>	<p style="text-align: right;">Page 125</p> <p>1 NDMA in valsartan, he actually noted the root cause  2 for it; correct?  3 MS. ROSE: Object to the form.  4 THE WITNESS: Yeah. And I heard his boss  5 say nobody at the company knew in the deposition.  6 BY MR. SLATER:  7 Q. What you heard the boss say is I don't  8 remember seeing the e-mail. That's what you  9 remember him saying under oath; right?  10 MS. ROSE: Object to the form.  11 MR. SLATER: Why are you objecting?  12 MS. ROSE: You're putting words --  13 MR. SLATER: What's the basis for that  14 objection?  15 MS. ROSE: You're misstating his prior  16 testimony completely.  17 MR. SLATER: No, I'm not.  18 BY MR. SLATER:  19 Q. You can go ahead, Doctor.  20 A. Two different things. They didn't see  21 the e-mail. No one at the company knew. He didn't  22 have to see the e-mail to know that no one at the  23 company knew.  24 Q. Did it ever occur to you --  25 A. -- putting those two together.</p>

<p style="text-align: right;">Page 126</p> <p>1 Q. Okay. Rephrase. When you were 2 evaluating this e-mail, did it occur to you that 3 maybe the people at ZHP didn't want to admit under 4 oath that there were people in the company that 5 knew there was NDMA in valsartan in July of 2017? 6 Did that occur to you that maybe they didn't want 7 to admit that they knew about this and didn't tell 8 the world because of how massive of a regulatory 9 violation that would be? 10 MS. ROSE: Object to form. 11 BY MR. SLATER: 12 Q. I just want to know if you took into 13 account that possible explanation. 14 A. If I took that into account, I 15 wouldn't -- I wouldn't use it because it's a total 16 speculation on their behavior that I have no reason 17 to -- no basis to support. 18 Q. Well, you're speculating that 19 this -- that this sentence just somehow magically 20 got into the e-mail by mistake. Isn't that 21 speculation? 22 MS. ROSE: Object to form. 23 THE WITNESS: The sentence is complete -- 24 sorry. The sentence is a complete non sequitur, so 25 I can't fit it in the rest of the topics.</p>	<p style="text-align: right;">Page 128</p> <p>1 withdraw that. 2 You have no information, no basis to 3 say that that phrase in that sentence that we're 4 talking about, "It is similar to 5 N-nitrosodimethylamine that occurs in valsartan 6 when quenched with sodium nitrite, and its 7 structure is very toxic," you have no basis to say 8 that that sentence was not intended to be in this 9 e-mail; correct? 10 A. The basis I have is that it's a non 11 sequitur with all the other topics. 12 Q. Isn't it possible that this person who 13 was an expert at evaluating impurities in drug 14 substance was comparing this impurity he was seeing 15 in this irbesartan substance to an impurity he knew 16 existed in valsartan? That's possible; right? 17 A. He would be comparing it to impurity K, 18 not to NDMA. 19 Q. He doesn't say impurity K. He says NDMA; 20 right? 21 A. He -- he attaches a patent that talks 22 about -- 23 Q. That's later in the e-mail. 24 MS. ROSE: Please -- 25 BY MR. SLATER:</p>
<p style="text-align: right;">Page 127</p> <p>1 BY MR. SLATER: 2 Q. Actually, the sentence makes perfect 3 sense. And I'll tell you why. And you tell me if 4 you agree. Let me ask the question differently. 5 He is characterizing this nitrosamine 6 he's seeing in this irbesartan substance they're 7 experimenting with, and compares it to another 8 nitrosamine that he states they know occurs in 9 valsartan and is caused by sodium nitrite. So he's 10 actually comparing what they're seeing here in the 11 irbesartan to something they know exists in the 12 valsartan, and then says, "and its structure is 13 very toxic." 14 That makes sense. That's what you 15 would expect a chemist to do, is say this looks 16 like something else we already know exists. That 17 makes sense, doesn't it? 18 A. So all of those -- that and nitroso and 19 impurity K are N-nitrosos on the sartan backbone, 20 and NDMA is a completely different molecule. No, 21 the comparison does not make sense. 22 Q. Okay. I would like you to assume that 23 Jinsheng Lin actually intended to write into this 24 e-mail what he wrote, okay? 25 Well, let me ask you this. Let me</p>	<p style="text-align: right;">Page 129</p> <p>1 Q. I'm talking about this sentence. 2 MS. ROSE: Mr. Slater, please do not cut 3 off the witness when he's in the middle of an 4 answer. 5 MR. SLATER: I'm not really sure if 6 there's an answer, or what's going on. 7 BY MR. SLATER: 8 Q. Doctor, you want to talk about impurity 9 K. That gets mentioned at the bottom of the 10 e-mail; right? Actually, impurity K doesn't even 11 get mentioned. There's a reference to a patent at 12 the bottom of the e-mail. 13 A. And in the patent -- in the patent it 14 talks about impurity K. The whole topic is about 15 nitrosations on the nitrogen atom of the sartan 16 backbone, not on the nitrosation of a completely 17 different molecule. 18 Q. Let's take the phrase, "It is similar to 19 the NDMA that occurs in valsartan when quenched 20 with sodium nitrite." 21 You'll agree with me that based on 22 that, on its face, Jinsheng Lin knew that there was 23 NDMA in valsartan, and it was formed as a result of 24 sodium nitrite quenching. And he knew that as of 25 the day he wrote the e-mail. If you take it on its</p>



<p style="text-align: right;">Page 130</p> <p>1 face, whether you think that sentence belongs in 2 the e-mail or not, he knew that; right? 3 A. You can interpret it however you want. I 4 don't interpret it that way. 5 Q. So you think he said that and it was just 6 a massive coincidence that he mentioned something 7 that happened to be absolutely true at the time, 8 and you think it's just complete coincidence that 9 it got in there in some kind of happenstance of 10 fate? 11 A. Yes. 12 Q. Do you think it was a massive wild guess? 13 MS. ROSE: Object to the form. 14 BY MR. SLATER: 15 Q. Let me ask this. Let me withdraw that. 16 This guy's job was to identify 17 impurities and the root cause for impurities; 18 right? 19 A. Yes. 20 Q. And that's what he's talking about in 21 that phrase, "NDMA is in valsartan, and the root 22 cause is sodium nitrite quenching." That's what 23 his job is, is to say things like that; right? 24 MS. ROSE: Object to the form. 25 THE WITNESS: I think he was pointing</p>	<p style="text-align: right;">Page 132</p> <p>1 will be very strong and there will be an extremely 2 high GMP risk." Do you see what I just read? 3 A. Yes. 4 Q. He then states, "This is a common problem 5 in the production and synthesis of sartan APIs." 6 You see that? 7 A. I do. 8 Q. And you know as you sit here right now 9 that multiple sartans turned out to have this exact 10 problem due to sodium nitrite quenching. You know 11 that as you sit here right now; right? 12 A. I know of two sartans where nitrosations 13 of the sartan backbone is a problem from sodium 14 nitrite. I know of two. 15 Q. Which two do you know about? 16 A. Irbesartan and impurity K. 17 Q. What about valsartan? 18 A. Valsartan is a deacylated version -- I 19 mean impurity K is a -- comes from a deacylated 20 version of valsartan. So that's -- that's -- 21 that's the nitrogen that I'm talking about when I 22 say impurity K getting nitrosated. Not clear? I 23 know of two. You asked me if it's a common 24 problem, and I said I know of two. 25 Q. So you're drawing a distinction where</p>
<p style="text-align: right;">Page 131</p> <p>1 out -- I said it's my -- he was pointing out this 2 would be a problem of a similar magnitude of NDMA 3 forming in valsartan from sodium nitrite. If you 4 look at the list of all the cohort of concerns, the 5 first one on the list is always NDMA. He pulled 6 the first one off the list and used that for his 7 comparison. I gotta take a leak. Can we -- is 8 that okay? 9 MR. SLATER: Sure. 10 THE WITNESS: I mean, do you want to go 11 on, or -- 12 MR. SLATER: No, we can take a break. 13 You go to the bathroom and come on back. 14 THE WITNESS: Okay. Thank you. Be right 15 back. 16 THE VIDEOGRAPHER: We're off the record 17 at 2:03 p.m. 18 (Break taken.) 19 THE VIDEOGRAPHER: Back on the record at 20 2:05 p.m. 21 BY MR. SLATER: 22 Q. Let's go down to the paragraphs 23 underneath the diagrams. The second paragraph 24 under the diagrams, it says, "If it is confirmed as 25 the above-speculated structure, then its toxicity</p>	<p style="text-align: right;">Page 133</p> <p>1 something's deacylated? 2 A. If it's not deacylated, it's not going to 3 form an N-nitroso compound. 4 Q. So are you aware that N-nitroso compounds 5 formed in valsartan, irbesartan, and losartan? 6 A. I don't know about losartan. I've never 7 seen one. 8 Q. Okay. 9 A. But I don't know about that. That's why 10 I said I only know of two. 11 Q. One possibility is that Jinsheng Lin 12 knew, as of July 27, 2017, that NDMA was occurring 13 in the valsartan that ZHP was manufacturing and the 14 root cause was the sodium nitrite quenching? That 15 is possible from this e-mail; correct? 16 A. That's a possibility. 17 Q. Let's go down now to the last paragraph. 18 After the whole discussion in the e-mail, at the 19 very end Jinsheng Lin says, "I've also attached a 20 patent of a 2013 sodium azide NaClO quenching 21 method by Zhejiang's Second Pharma Company 22 Limited. They proposed that the use of NaNO2 23 quenching" -- that would be sodium nitrite 24 quenching; right? 25 A. Right.</p>

<p style="text-align: right;">Page 134</p> <p>1 Q. -- "will result in the formation of N-NO 2 impurities"; right? 3 A. Yes, that's what it says. 4 Q. So let's stop there. Did you read the 5 patent? 6 A. I did. 7 Q. And that patent was from 2013; right? 8 A. Yes. 9 Q. And did you see in the deposition 10 testimony that that patent was in ZHP's files as of 11 2014? 12 A. I think I remember seeing that, yes. 13 Q. And therefore ZHP was aware, at least as 14 of 2014, if not earlier, that sodium nitrite 15 quenching will result in the formation of 16 nitrosamine impurities; right? 17 A. Impurity K. 18 Q. That's not what this e-mail says, sir. 19 So I'm asking you what it says. 20 A. Well, that's what it implies. Everybody 21 knew about impurity K. 22 Q. Is impurity K -- 23 A. That -- 24 Q. -- a nitrosamine? 25 A. That paragraph does not imply --</p>	<p style="text-align: right;">Page 136</p> <p>1 the language says in the e-mail; right? Is that 2 what the e-mail says? 3 A. Yeah, when you look at the patent, it 4 talks about impurity K. 5 Q. Now I have to ask the question again. 6 A. Okay. 7 Q. I'm going to make a promise to you. 8 We're going to talk about the patent. I don't have 9 any idea why you-all think that patent helps you, 10 but we'll talk about it, okay? 11 MS. ROSE: All right. Object to the 12 characterization. 13 MR. SLATER: I don't know why it keeps 14 getting thrown in, so I get to a 15 characterization -- 16 THE WITNESS: I think it -- 17 MS. ROSE: He's trying to answer your 18 question. 19 THE WITNESS: I think it clarifies, you 20 know -- 21 BY MR. SLATER: 22 Q. I didn't ask you to clarify it, though. 23 I just asked you what the document said. 24 A. So are you saying I can't clarify 25 statements?</p>
<p style="text-align: right;">Page 135</p> <p>1 THE WITNESS: Nina, you want to talk? 2 Nina, you're on mute. Can't hear you. 3 MS. ROSE: I apologize. Hopefully my 4 objections have been coming through. But you've 5 been cutting off the witness. Please let him 6 answer the question. 7 THE WITNESS: My feelings aren't hurt. 8 So that paragraph doesn't say anything about NDMA. 9 That's not what it talks about. It's talking about 10 impurity K. It's talking about -- it's talking 11 about impurity K. 12 BY MR. SLATER: 13 Q. Let's look at what this scientist, whose 14 job it was to determine the root causes of 15 impurities, what he actually said in the e-mail. 16 Can we do that? 17 A. Sure. 18 Q. You've never spoken to Jinsheng Lin; 19 right? 20 A. I have not. 21 Q. So let's look at his actual e-mail. His 22 e-mail says that this other company, Zhejiang 23 Second Pharma Company, proposed that the use of 24 sodium nitrite quenching will result in the 25 formation of nitrosamine impurities. That's what</p>	<p style="text-align: right;">Page 137</p> <p>1 MS. ROSE: I apologize. Please do not 2 cut off the witness and not badger the witness. He 3 can -- ask your questions. He's answering your 4 questions. 5 BY MR. SLATER: 6 Q. Right. Let's try to answer my questions. 7 If I want clarification, I'll say by the way, give 8 me clarification. I'm just asking simple 9 questions. If I ask you what the document says, 10 I'm not sure why you're explaining something else. 11 That's my question to myself. Why is he talking 12 about this other thing? I just asked him this. 13 That's where my consternation comes from. 14 A. Well, the question is implying -- 15 Q. No, it's not, actually. 16 MS. ROSE: Again, Adam, please stop 17 cutting -- 18 MR. SLATER: There's not even a question 19 pending, Nina. I explained to him why I was 20 getting frustrated. I'm being very nice and 21 polite. We like each other. He's a nice guy. I 22 like Dr. Thompson. We're both doing our jobs. But 23 I'm just explaining, and he's just starting to 24 explain something else. There wasn't even a 25 question. So I'm allowed to say hey, let me get to</p>



<p style="text-align: right;">Page 138</p> <p>1 the next question.</p> <p>2 MS. ROSE: You're just making speeches on</p> <p>3 the record then if you're not asking questions,</p> <p>4 which I think is unfair to the witness and</p> <p>5 extending this process more than it needs to.</p> <p>6 MR. SLATER: Okay. All right. Well, I</p> <p>7 appreciate that. And I agree with you. This</p> <p>8 is -- we don't need any of this. What we need is</p> <p>9 to ask a question and answer a question. So I'm</p> <p>10 going to try it.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. He says that this other company proposed</p> <p>13 that the use of sodium nitrite quenching will</p> <p>14 result in the formation of nitrosamine impurities;</p> <p>15 correct? That's the words on the page?</p> <p>16 A. Yes.</p> <p>17 Q. And in the patent it talks about the</p> <p>18 formation of a nitrosamine impurity called impurity</p> <p>19 K; right?</p> <p>20 A. Yes.</p> <p>21 Q. So as least as of 2014, if not earlier,</p> <p>22 at least Jinsheng Lin was aware that another</p> <p>23 company had figured out that sodium nitrite</p> <p>24 quenching could result in the formation of a</p> <p>25 nitrosamine impurity in valsartan. In the case of</p>	<p style="text-align: right;">Page 140</p> <p>1 spectrometry, to identify the impurity; correct?</p> <p>2 MS. ROSE: Object to the form.</p> <p>3 THE WITNESS: Identified the</p> <p>4 impurity -- sorry. Sorry, Nina. Sorry.</p> <p>5 MS. ROSE: Go ahead, Dr. Thompson.</p> <p>6 THE WITNESS: Identified impurity K.</p> <p>7 Yes, they did.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. Okay. So you'll agree with me that in</p> <p>10 China, at least, we know that pharmaceutical</p> <p>11 companies, when they couldn't identify an impurity,</p> <p>12 could and did use mass spectrometry to identify</p> <p>13 what those impurities were. That's what this is</p> <p>14 showing us; right?</p> <p>15 A. Yeah, when they saw the peak, they were</p> <p>16 triggered to use LC mass spec, yes.</p> <p>17 Q. And that's because a company should never</p> <p>18 ignore -- well, forget it. I'm not going to go</p> <p>19 there because -- I'm not going to go there.</p> <p>20 A. You were going say to say they shouldn't</p> <p>21 ignore what they can't see?</p> <p>22 Q. No, I actually wasn't going to say that.</p> <p>23 But we'll move along.</p> <p>24 A. Okay.</p> <p>25 Q. Let's look at the last two sentences of</p>
<p style="text-align: right;">Page 139</p> <p>1 the patent it described impurity K. True</p> <p>2 statement?</p> <p>3 MS. ROSE: Object to the form.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. That's correct; right?</p> <p>6 A. So the -- impurity K and NDMA are worlds</p> <p>7 apart. They're not the same thing. If I see</p> <p>8 impurity K, I'm not thinking NDMA. Two different</p> <p>9 planets in terms of structure and how they come</p> <p>10 about. That's my clarification.</p> <p>11 Q. You agree with me that sodium nitrite</p> <p>12 quenching causes the formation of nitrosamine</p> <p>13 impurities in valsartan; right?</p> <p>14 A. The way they ran the -- yeah, according</p> <p>15 to item four it did, yes.</p> <p>16 Q. Let's go to the next sentence in this</p> <p>17 paragraph. The second sentence says, "At the same</p> <p>18 time, they" -- meaning this other Chinese</p> <p>19 pharmaceutical company -- "used ZHP's crude</p> <p>20 valsartan in their LCMS test and detected this</p> <p>21 impurity." Do you see that?</p> <p>22 A. Yes, I do.</p> <p>23 Q. So it's saying that this other</p> <p>24 pharmaceutical company in China, at least as of</p> <p>25 2013 when the patent was dated, used LCMS, mass</p>	<p style="text-align: right;">Page 141</p> <p>1 the e-mail. This indicates that other companies</p> <p>2 have paid attention to the quality problem very</p> <p>3 early on. You see that?</p> <p>4 A. Yes.</p> <p>5 Q. The quality problem is the formation of</p> <p>6 nitrosamine impurities due to sodium nitrite</p> <p>7 quenching. That's what he's talking about in this</p> <p>8 e-mail; right?</p> <p>9 A. Yeah, the quality problems in impurity K.</p> <p>10 Or this one irbesartan. Yes, that's a quality</p> <p>11 problem.</p> <p>12 Q. He also mentioned up above in the e-mail</p> <p>13 that what was being seen in the irbesartan was</p> <p>14 similar to the NDMA that occurs in valsartan</p> <p>15 when quenched with sodium nitrite, which he</p> <p>16 said -- rephrase.</p> <p>17 He also said above that what was seen</p> <p>18 in the irbesartan was similar to the NDMA that</p> <p>19 occurs in valsartan when quenched with sodium</p> <p>20 nitrite. He also said that in the e-mail; correct?</p> <p>21 A. Yes, he said that.</p> <p>22 Q. And in the last sentence, after pointing</p> <p>23 out this quality problem, he says, "So leaders,</p> <p>24 please pay attention to this issue." You see that</p> <p>25 sentence?</p>

<p style="text-align: right;">Page 142</p> <p>1 MS. ROSE: Object to the form.  2 THE WITNESS: Yeah.  3 BY MR. SLATER:  4 Q. Remember you asked me at the beginning of  5 the deposition -- or you stated out as a question  6 sort of to the world -- rephrase.  7 You remember at the beginning of the  8 deposition you questioned why would he send this  9 e-mail to all these high level people in the  10 company? Remember you said that?  11 A. Yeah.  12 Q. Well, now you see at the end he says, "So  13 leaders, please pay attention to this issue," the  14 issue being a quality problem that other companies  15 have noticed. Do you see that?  16 A. So none of those people can take -- can  17 do anything about it. They're not process  18 chemists. They can't make a change. All they can  19 do is say why am I getting this e-mail.  20 Q. Couldn't they also say, hey, this guy's  21 pointing out to us a quality problem we have with  22 the manufacturer of our sartans, and he's literally  23 telling them to beware because other companies are  24 catching on to this problem?  25 MS. ROSE: Object to form.</p>	<p style="text-align: right;">Page 144</p> <p>1 Q. He sent it to Peng Dong, who's the head  2 of the analytical department, right? The technical  3 department, I mean.  4 A. No analytical chemist tells a synthetic  5 chemist how to run their reactions. It's  6 ridiculous.  7 Q. You have Lihong Lin. She was the head of  8 regulatory for the whole company. Did you know  9 that?  10 A. Yeah. As -- again, I never saw a  11 regulatory fast person walk into the process lab  12 and say run your reaction differently. That never  13 happened.  14 Q. Dr. Thompson, do you realize what  15 happened when the world found out that there was  16 NDMA in the valsartan?  17 A. Yeah, they immediately recalled it.  18 Q. It was a big problem; right?  19 A. Yes. They -- they reacted responsibly.  20 They immediately recalled it.  21 Q. And that was because, as Jinsheng Lin  22 described it, toxicity would be very strong and an  23 extremely high GMP risk; right?  24 MS. ROSE: Object to the form. Object,  25 outside the scope.</p>
<p style="text-align: right;">Page 143</p> <p>1 BY MR. SLATER:  2 Q. That's a responsible thing to do when  3 your job is to identify impurities in a drug  4 substance that your company's manufacturing. If  5 you see a dangerous problem, you let the people at  6 the top of the company know, hey, we have an issue  7 we need to take care of. That's responsible;  8 right?  9 MS. ROSE: Object to the -- Dr. Thompson,  10 give me one second. Object to the form. Object to  11 the speech.  12 THE WITNESS: I totally disagree. His  13 responsibility, if he thought that, was to get in  14 touch with the head of process research and say  15 we've got a problem here. This is a chemistry  16 problem. Let's take care of it, instead of sending  17 it to a quality control person who doesn't have any  18 control over what happens in the chemistry and  19 their reactors. He sent it to the wrong people.  20 BY MR. SLATER:  21 Q. Well, he sent it to his boss, Min Li;  22 right? He is that -- one of the people, right, who  23 got it?  24 A. Yeah. No chemists. No process chemists.  25 It's weird. That's weird.</p>	<p style="text-align: right;">Page 145</p> <p>1 BY MR. SLATER:  2 Q. Or is that beyond your scope of your  3 opinion?  4 A. Well, when I look at the N-nitroso  5 compound from irbesartan, that's not a risk. That  6 doesn't look like a toxic compound. So he's being  7 a little ignorant in his evaluation of what -- he  8 sees N-NO and says toxic without any depth of  9 understanding.  10 And I also read from Min Li's  11 deposition that impurity K was qualified at a  12 thousand -- at a thousand PPM by Novartis. So  13 he's -- he's mischaracterizing the toxicity of  14 these compounds, and he's sending it to the wrong  15 people. And it's his opinion. There's just no  16 data that -- there's just -- it's off.  17 Q. Sorry. Doctor, did you say there's no  18 data? The statement that there's NDMA in valsartan  19 caused by sodium nitrite quenching is an absolutely  20 correct statement. We already talked about that.  21 A. Yeah.  22 MS. ROSE: Object to the form.  23 BY MR. SLATER:  24 Q. Doctor, that's a correct statement;  25 right?</p>

<p style="text-align: right;">Page 146</p> <p>1 A. Where's the data to back it up? Where's 2 the data prior to this e-mail to back it up? 3 Q. That's a good question. You would think 4 that they -- it would have been produced to us; 5 right? 6 MS. ROSE: Object to the form. Adam, 7 please, bringing in your discovery theories into an 8 expert deposition is very inappropriate. 9 MR. SLATER: I think I can ask any 10 question I want. I'm being told that -- things 11 that I think makes these comments and questions 12 very appropriate, because Dr. Thompson needs to 13 know what position he's taking and what might come. 14 THE WITNESS: Yeah, the fact that there's 15 no data results that should be present if they knew 16 that, if he ran those experiments and knew it, 17 there would be data. And there's no data. I 18 haven't seen data. That's really the right way 19 to -- I haven't seen the data. If it was 20 available, it would be produced. So without data, 21 that sentence really doesn't carry as much weight 22 as you may think. 23 BY MR. SLATER: 24 Q. So it's just an isolated, lucky guess, 25 huh?</p>	<p style="text-align: right;">Page 148</p> <p>1 MS. ROSE: Object to the form. 2 THE WITNESS: Yes. Oh, sorry. Yes. 3 BY MR. SLATER: 4 Q. And that's exactly what the patent talked 5 about; right? 6 A. Yes. 7 Q. And what they did is they replaced the 8 sodium nitrite with something called hypochlorite 9 so it would not be capable of producing a 10 nitrosamine; correct? 11 A. Yeah. That's bleach, by the way. 12 Q. Am I correct? 13 A. Yes. I think that by doing that, they 14 would have had a worse problem, a worse process. 15 Q. So going back to your report now, I want 16 to look at the attachments. Exhibit 1 is your CV; 17 right? 18 A. Hold on. I'm trying to get back there. 19 Let's see. I'm back to my report. What exhibit is 20 that, two? 21 Q. Exhibit 1 is your CV, your curriculum 22 vitae; correct? 23 A. Yes. 24 Q. And that's up to date? 25 A. No, Exhibit 1 is the deposition notice.</p>
<p style="text-align: right;">Page 147</p> <p>1 MS. ROSE: Object to the form. 2 BY MR. SLATER: 3 Q. I mean, it was just an isolated, lucky 4 guess that there was NDMA in valsartan in 2017 that 5 was forming due to sodium nitrite quenching? Is 6 that your testimony, Doctor? 7 MS. ROSE: Object to the form. 8 THE WITNESS: As I said before, if you 9 look at a table of the cohort of concerns, the 10 first nitrosamine in every table is NDMA. He 11 picked the first one. It's not a lucky guess. 12 BY MR. SLATER: 13 Q. Which table are you talking about? 14 A. Any table I've looked at where they 15 list -- the regulatory -- that toxicology and 16 regulatory affairs paper that you'll look at later. 17 There's a table in there. I'm pretty sure the 18 first one is NDMA. You go to a table, you pick 19 up -- the first one you see, you put it in the 20 e-mail. 21 Q. Is that a document you have in your file? 22 A. Yes. You have it now. 23 Q. Okay. You think that it was a good idea 24 to try to avoid the creation of nitrosamine 25 impurities in sartans?</p>	<p style="text-align: right;">Page 149</p> <p>1 Q. No, no, no. I'm talking about your 2 report, which is Exhibit 4, has two exhibits to it. 3 A. Okay. Yeah. Okay. All right. 4 Q. The first exhibit to your report is your 5 curriculum vitae; correct? 6 A. Yes. 7 Q. And that's up to date? 8 A. Yes. 9 Q. You have a list of patents; correct? 10 MS. ROSE: I want to make clear we 11 produced an additional CV in response to your 12 request for an up-to-date CV prior to the 13 deposition. So this is the CV at the time he 14 submitted his report. 15 BY MR. SLATER: 16 Q. Were there any changes made to the CV 17 between the time you served the report and whatever 18 was sent to us more recently? 19 A. Yeah, I added a number of patents. I 20 added all the compounds I worked on that became 21 commercial, and I added a few more publications as 22 well. But if you're talking about a certain patent 23 I think you're talking about, that didn't change. 24 Q. All right. We're going to put your 25 up-to-date CV up then.</p>

<p style="text-align: right;">Page 150</p> <p>1 A. Okay, great. You're going to display it 2 on the share screen? This is the up-to-date one? 3 Okay, great. 4 MS. ROSE: Is this being introduced as an 5 exhibit? 6 MR. SLATER: I'm trying to get there. 7 MS. ROSE: Okay. 8 MR. SLATER: Exhibit 7 now. 9 MS. ROSE: I just want to make sure the 10 doctor has access to the document on the share 11 file. 12 BY MR. SLATER: 13 Q. Exhibit 7 is the up-to-date curriculum 14 vitae we were produced. So Doctor, this is what I 15 want to ask you -- 16 MS. ROSE: It just hasn't come through 17 yet, Adam. Okay, now it's through. I just want to 18 make sure the doctor has the opportunity to look at 19 what you're -- 20 THE WITNESS: Okay. I don't really need 21 to. I know it well enough that I'll just depend on 22 the shared screen for this one. 23 BY MR. SLATER: 24 Q. Who knows, maybe I'll ask a couple easy 25 questions.</p>	<p style="text-align: right;">Page 152</p> <p>1 was Ministry and Industry Information Technology of 2 the People's Republic of China, Chemical Industry 3 Standard of People's Republic of China, 4 Dimethylamine For Industrial Use published 5 December 4, 2009. Do you see that? 6 A. Yes. 7 Q. Did you read that document? 8 A. That's the one -- that's the one with all 9 the description of the test methods on the CMA. Is 10 that the one -- is that the one that is? 11 Q. The Chinese standards as described, I 12 think it has some test methods in it for COAs. 13 A. I believe I did read that one, yes. 14 Q. And then at the bottom there's four 15 documents with ZHP Bates numbers. Do you see that? 16 A. Yeah. 17 Q. When did you get those additional 18 materials, those five new documents that were added 19 to your list of materials? 20 A. I'd say last week. 21 Q. Did you know they existed before the last 22 week, or is that when you first found out they 23 existed? 24 A. Well, I was aware that ZHP had a lot of 25 certificates of analysis for every batch of</p>
<p style="text-align: right;">Page 151</p> <p>1 A. Put me to sleep then. 2 Q. In your curriculum vitae, this up-to-date 3 one we marked as Exhibit 7, there's a list of 4 patents. Are any of them relevant to the issues 5 that you're opining on in this case? 6 A. No. 7 Q. In your CV we marked as Exhibit 7, 8 there's a list of research publications. Are any 9 of them relevant to the issues that you're opining 10 on in this case? 11 A. No. 12 Q. Let's go to Exhibit 2. We'll come to the 13 amended, don't worry. Looking now at Exhibit 2 to 14 your report, which is Exhibit 4. As of the time 15 you wrote the report, this was the list of 16 materials that you considered? 17 A. Yes. 18 Q. And the opinions set forth in your report 19 are based on these materials; correct? 20 A. Yes. 21 Q. And then let's put up as Exhibit 8 the 22 up-to-date amended Exhibit 2, please. 23 In looking at this document, at the 24 end there's a list of other materials. And it 25 looks like five documents were added, one of which</p>	<p style="text-align: right;">Page 153</p> <p>1 dimethylamine, so I knew that they must have 2 existed. 3 Q. How did you know that? 4 A. Because generally GMP purposes, you can't 5 accept a material for use unless you approve it. 6 And part of the approval process is the certificate 7 of analysis from the supplier. 8 Q. When you got these materials, we got no 9 supplemental report from you. So I'm assuming they 10 did not change any of your opinions? 11 A. No, they did not. 12 Q. Let's put up -- I think it's exhibit -- 13 are we up to eight now, or nine? 14 MR. GEDDIS: Nine. 15 MR. SLATER: Exhibit 9 is going to be the 16 English translation of that standard. 17 THE WITNESS: Okay. Yep. 18 BY MR. SLATER: 19 Q. Okay. Is there anything about this 20 standard that's of any significance to you in 21 forming your opinions in this case? 22 MS. ROSE: Has this been introduced as an 23 exhibit? 24 MR. SLATER: Let me ask the question 25 differently. This is Exhibit 9.</p>

<p style="text-align: right;">Page 154</p> <p>1 MS. ROSE: Okay. I apologize. Thank 2 you. 3 BY MR. SLATER: 4 Q. Doctor, is there anything of any 5 significance to you in this document? 6 A. I mean, this describes -- scroll down. 7 Is there a certificate of analysis in here? 8 MS. ROSE: Doctor, you have access to 9 this document on the share site. 10 THE WITNESS: No, I really have to take a 11 look at the document. What is that, 9? 12 BY MR. SLATER: 13 Q. Yes. 14 A. Okay. So let's see. There is -- oh, 15 yeah, there's a -- a mock certificate of analysis 16 that has the testing methods. So the question is 17 is anything in this document pertinent to my 18 opinions? Is that what -- 19 Q. Was anything that you read in this 20 document significant to you? 21 A. The only significance it was -- so I 22 could understand the test methods and how they're 23 run for entering the data analysis. That was the 24 significance. I got a deeper understanding of how 25 they test DMF, what they actually do.</p>	<p style="text-align: right;">Page 156</p> <p>1 in the last week? 2 A. This -- this certificate of analysis? 3 Q. This standard. This document. Had you 4 ever seen this before -- 5 A. No. 6 Q. -- a week ago? 7 A. No. 8 Q. Have you ever worked with this document 9 before? 10 A. No. 11 Q. Have you -- do you hold yourself out as 12 an expert in the interpretation of this document? 13 MS. ROSE: Object to the form. 14 THE WITNESS: Highly skilled, not an 15 expert. 16 BY MR. SLATER: 17 Q. The words on the page say that the 18 alkalinity is calculated as dimethylamine; correct? 19 A. That's what the words say. That's what's 20 unclear about it. 21 Q. I have to ask the question again. The 22 word on the page says alkalinity calculated as 23 dimethylamine weight by percentage. That's what it 24 says; right? 25 A. That's what it says.</p>
<p style="text-align: right;">Page 155</p> <p>1 Q. When you got that understanding, was that 2 significant to you once you learned that 3 information? 4 A. So the alkalinity test is -- is one that 5 it was unclear. The wording says, you know, an 6 alkalinity of eight percent as a function 7 calculated as dimethylamine. And that wording was 8 a little unclear. So by reading this document, it 9 became clear what that wording actually meant. 10 Q. What became clear to you? 11 A. So, yeah, that's total base content. 12 That's not -- that's not necessarily dimethylamine, 13 it's total base content. It could be 14 dimethylamine. It could be carbonate. It could be 15 a few things. So that's -- it's a molecular weight 16 of dimethylamine. That's the number in the 17 formula. 18 Q. Let's go to page 2 of this document, 19 table one, the technical requirements. 20 A. Yes. 21 Q. You see where it says alkalinity in the 22 left-hand column? 23 A. Alkalinity calculated as dimethylamine. 24 Q. Are you -- let me ask you this. Have you 25 ever seen this standard before it was given to you</p>	<p style="text-align: right;">Page 157</p> <p>1 Q. Now let's look at page 6. You see 2 there's a 4.9.5 result calculation. Do you see 3 that heading? 4 A. Yes. 5 Q. It says, "The mass fraction of alkalinity 6 calculated as dimethylamine W5 is expressed as a 7 percent and calculated using the formula." And you 8 see the formula there? 9 A. I do. 10 Q. And if you go down to the inputs, you see 11 that one of the inputs is an M, a capital M? 12 A. Yes. 13 Q. And you see where it says that M equals 14 molar mass of dimethylamine in grams per mole. Do 15 you see that? 16 A. Yes. 17 Q. So that's telling you that one of the 18 inputs to the calculation is the molar mass of 19 dimethylamine in grams per mole. That's what this 20 calculation states; correct? 21 A. That's the mo -- that term M is the 22 molecular weight of dimethylamine. It's not 23 necessarily the dimethylamine content. It's the 24 molecular weight. So the difference is there could 25 be a bunch of different bases in there. It's the</p>



<p style="text-align: right;">Page 158</p> <p>1 total base content, not specifically one. 2 Dimethylamine is a base. It's not specifically 3 that, it's total. Everything. 4 Q. Let's go with what you just said. One of 5 the bases could be dimethylamine? 6 A. I said -- I said that -- yeah, one of the 7 bases could possibly be, yes. 8 Q. So ZHP was aware that one of the 9 potential inputs coming to this manufacturing 10 process with the DMF would be dimethylamine. 11 That's what this is telling us; right? 12 MS. ROSE: Object to the form. 13 BY MR. SLATER: 14 Q. It's a potential input to the process 15 dimethylamine; correct? 16 A. At such a low level no one would pay 17 attention to it. 18 Q. New question. One of the things this is 19 telling us is that ZHP was aware that one of the 20 potential inputs to the process when using DMF was 21 dimethylamine; correct? 22 MS. ROSE: Object to the form. 23 THE WITNESS: I mean the analytical 24 chemist who filed this document might say that, 25 but -- okay, yes. No, I won't say yes to that. I</p>	<p style="text-align: right;">Page 160</p> <p>1 using DMF, one of the potential inputs to the 2 process, along with the DMF, could be 3 dimethylamine; correct? 4 MS. ROSE: Object to the form. 5 THE WITNESS: Yeah, at a number so low 6 you ignore it, but yes. 7 BY MR. SLATER: 8 Q. I'll ask it again. Sorry. 9 A. Okay. 10 Q. I didn't ask you about what they do 11 with -- the expert on what they do with the 12 information. So I'm not asking you what they do 13 with the information. So I'm not sure why you're 14 throwing that in. You already told me that's not 15 your role here; right? 16 A. Right. 17 Q. Okay. So let me just limit it to the 18 question I'm trying to ask, please. 19 One of the things this standard shows 20 us is that ZHP would have been aware that when it 21 used DMF, that, along with the DMF, dimethylamine 22 could also be introduced to the process; correct? 23 A. Yes. 24 MS. ROSE: Object to the form. 25 THE WITNESS: Oh, sorry. Yes.</p>
<p style="text-align: right;">Page 159</p> <p>1 don't think ZHP was aware. Some low-level working 2 people who file documents saw that and said that's 3 just a number of base. That's how they calculated 4 it. I don't think -- I don't think anybody who saw 5 that, who had access to this document, could 6 interpret that in terms of how it would affect the 7 chemistry in the plant. No way. 8 BY MR. SLATER: 9 Q. Didn't ask you that at all. So please 10 try to stay with me on this question. 11 A. Okay. Sorry for diverting. 12 MS. ROSE: Please do not characterize 13 what the witness is doing. He's answered your 14 question. You asked a complicated question -- 15 MR. SLATER: You want to comment and tell 16 me that I got a responsive answer when I didn't? 17 I'm not going to be as receptive to what you say, 18 because we both have to be honest with each other, 19 okay? Come on. Please. I've been enormously 20 patient and taking my time through this deposition. 21 But I'll try again. And again, I like 22 Dr. Thompson. We're doing good. 23 BY MR. SLATER: 24 Q. I'll try it again. This standard is 25 telling us that ZHP would have been aware that when</p>	<p style="text-align: right;">Page 161</p> <p>1 BY MR. SLATER: 2 Q. And you've looked at the certificate -- 3 well, let me ask you this. Rephrase. 4 There's four certificates of analysis 5 listed at the bottom. And I pulled them out. And 6 they're all written in the Chinese language. Do 7 you see that? 8 A. Yes. 9 Q. Were those of any significance to you 10 whatsoever? 11 A. Yes. 12 Q. You read Chinese? 13 A. No. I was able to figure out what 14 the -- what the line items were after I read this 15 document. 16 Q. So you matched it up to that table -- 17 A. Yes. 18 Q. -- we looked at before? 19 A. Yes. 20 Q. And you saw that for two out of the four 21 certificates of analysis you were provided, there 22 actually was some alkalinity measured; correct? 23 MS. ROSE: Object to the -- object to the 24 form. Are you going to show him the document? 25 MR. SLATER: I'm asking the question I</p>

<p style="text-align: right;">Page 162</p> <p>1 just asked. I'm trying to save time.  2 MS. ROSE: It's just not a memory test.  3 So you're asking him to remember numbers in  4 documents.  5 MR. SLATER: Okay.  6 BY MR. SLATER:  7 Q. Do you remember looking at these  8 documents and seeing that two out of the four of  9 them actually calculated having some alkalinity on  10 that line?  11 A. The effect those numbers had on my  12 opinion was to reinforce it.  13 Q. Okay. My question is when you saw the  14 four certificates of analysis that you were  15 provided by ZHP, did you note that in two out of  16 those four, there was some alkalinity measured? It  17 wasn't zero. It was more than zero. I'm just  18 asking if you saw that.  19 A. Yes, I did.  20 Q. So with those certificates of analysis,  21 ZHP would have been aware that there was the  22 potential that per these suppliers' own certificate  23 of analysis, it was potentially -- it was  24 potentially true that the DMF also contained some  25 amount of dimethylamine. They would have been on</p>	<p style="text-align: right;">Page 164</p> <p>1 THE WITNESS: 2:50. You got it.  2 THE VIDEOGRAPHER: We're off the record  3 at 2:41 p.m.  4 (Break taken.)  5 THE VIDEOGRAPHER: We're back on the  6 record at 2:55 p.m.  7 BY MR. SLATER:  8 Q. Doctor, I'm going to ask you a few more  9 questions about Exhibit 9, those standards.  10 A. Yes. Sure.  11 Q. Let's go to the foreword. It's the third  12 page of the document. It has Roman numeral one.  13 It's the foreword. It's literally the third page  14 in.  15 A. Third page on that like the -- the  16 foreword. Okay, foreword. That's the page. Yeah.  17 Okay. I'm there.  18 Q. This points out in the -- so it's talking  19 about some revisions to the prior version of this  20 standard. And it says, "The scope" -- this is the  21 third line, "The scope has been revised from  22 'applicable to the production of industrial  23 dimethylformamide via the reaction of methylformate  24 with dimethylamine primarily used in  25 pharmaceuticals, pesticides, and organic chemicals</p>
<p style="text-align: right;">Page 163</p> <p>1 notice of that possibility; correct?  2 MS. ROSE: Object to the form.  3 THE WITNESS: I think they would have  4 been on notice not to worry about it.  5 BY MR. SLATER:  6 Q. Can you answer -- can you answer my  7 question?  8 They would have been on notice that  9 there was the potential for some dimethylamine to  10 be introduced to the process through this DMF.  11 They would have been on notice of that possibility;  12 correct?  13 MS. ROSE: Object to the form.  14 THE WITNESS: Yes.  15 MR. SLATER: Why don't we take a break  16 for a couple minutes. I want to look at my notes.  17 There's a couple things I'd like to do, but I'd  18 like to organize a little bit. And why don't we  19 come back in about, you know, five or six or  20 seven minutes, and then I'll let you know how much  21 more I have to do, and we'll get going.  22 THE WITNESS: Okay, great. Thank you.  23 MS. ROSE: If we could take ten minutes,  24 that would be helpful to me personally.  25 MR. SLATER: Nina, I am here for you.</p>	<p style="text-align: right;">Page 165</p> <p>1 to -- applicable to industrial dimethylformamide  2 synthesized by one-step carbon monoxide method and  3 the reaction of methylformate with dimethylamine."  4 Do you see that?  5 A. Yes.  6 Q. And that's how you manufacture  7 dimethylformamide, is by a reaction of  8 methylformate with dimethylamine; correct?  9 A. Yeah, that's what it says.  10 Q. Did you know that before you got involved  11 in this case, that that's how you create DMF?  12 A. I might have known that in the distant  13 past. It certainly got reinforced once I got  14 involved with this case.  15 Q. And let's go now back to the calculation  16 on page 6. You mentioned that the alkalinity could  17 be due to bases including dimethylamine and a few  18 other substances. Can you tell me again what those  19 substances are?  20 A. So hold on. Let me get to the equation.  21 The possibility -- so one of the possibilities  22 potentially -- I mean, the bases that would be  23 stable in DMF would be a carbonate base. Now I see  24 methoxide for methylformate. There could be  25 methoxide in there. There's a number of different</p>

<p style="text-align: right;">Page 166</p> <p>1 bases that could be in there. Not just -- there's 2 a number of different bases that could be in there. 3 Q. Well, I want to know the ones that you 4 can identify for me. You said carbonate base or 5 methoxide? 6 A. Carbonate base -- yeah, so methylformate 7 and methylamine, that will give off methanol, not 8 methoxide. So -- and I don't know if they used 9 carbonate in the process at all, if there are any 10 catalysts that use it. So this -- you know, I 11 don't know exactly if they just mix those two 12 ingredients with no catalyst and heat them up, or 13 what they do, but... 14 So I'm just -- you know, assuming 15 there's a catalyst, there could be things that come 16 off the catalyst that are bases, like carbonate. 17 You know, that's -- so that's a total base content. 18 Otherwise they would just say this is the amount of 19 dimethylamine in there. Why don't they say that? 20 Why do they say calculated as dimethylamine? There 21 must be other bases in there for them to make a 22 generic formula like that. 23 Q. You're speculating as to that; correct? 24 A. I'm speculating. 25 MS. ROSE: Object to form.</p>	<p style="text-align: right;">Page 168</p> <p>1 Q. I apologize. Okay. Apologize. 2 Technical issue. Hi, Doctor. How are you? 3 A. Hi. Good. 4 Q. I just have a few questions for you. 5 A. Okay. 6 Q. Dr. Thompson, would you agree that your 7 key opinion in this case is that you disagree with 8 the opinions of Drs. Hecht and Najafi that chemists 9 working in the pharmaceutical industry should have 10 known or suspected prior to 2018 that NDMA could 11 form in the valsartan manufacturing process? 12 A. Yes. 13 MR. SLATER: Object to the form of the 14 question. It's a leading question. Inappropriate. 15 You can answer. 16 THE WITNESS: Yes, I disagree with their 17 opinions. 18 BY MS. ROSE: 19 Q. And why is that? What is the basis for 20 your disagreement? 21 A. After I read the supporting documents 22 that they provided with their opinions, it was 23 clear to me that they were using hindsight to make 24 their -- to make their judgment. So that was one 25 thing.</p>
<p style="text-align: right;">Page 167</p> <p>1 THE WITNESS: Yeah, of course I'm 2 speculating. I'm sorry. Yes, I'm -- I didn't put 3 the formula together. I'm speculating. 4 BY MR. SLATER: 5 Q. The only base referenced here is 6 dimethylamine; correct? 7 A. Yes. 8 MR. SLATER: Dr. Thompson, I'm going to 9 conclude my direct questioning of you. I have all 10 this, but I'm going to try to avoid using it. So 11 hopefully your counsel doesn't ask a lot of 12 questions and I don't have to come back to all that 13 stuff. But subject to what questions are asked, 14 I'm done for now. So thank you. 15 THE WITNESS: Okay. Great. Thank you. 16 MS. ROSE: Can we go off the record? 17 THE VIDEOGRAPHER: We're off the record 18 at 3:00 p.m. 19 (Break taken.) 20 THE VIDEOGRAPHER: We're back on the 21 record at 3:35 p.m. 22 EXAMINATION 23 BY MS. ROSE: 24 Q. Hi, Doctor. 25 A. Nina, you just blanked out.</p>	<p style="text-align: right;">Page 169</p> <p>1 The other thing is my -- my -- in all 2 my experience as an organic chemist, I just think 3 that this issue had too many subtleties involved 4 with it for people to recognize the problem. And 5 the last thing is the -- you know, there were two 6 regulatory bodies that reviewed these amendments. 7 There was two amendments and two regulatory bodies. 8 That means there was four different reviews by 9 regulatory bodies with the goal of looking at this 10 thing in terms of safety. That was the goal of 11 evaluating it. Not a single person brought up the 12 issue of NDMA formation. Four -- four chemists 13 from regulatory bodies, zero brought up the issue. 14 So I really don't think it's -- you 15 can make a statement that chemists would have known 16 this issue. I think from the evidence, it's the 17 opposite. Chemists would not have recognized this 18 issue. 19 Q. Dr. Thompson, do you recall that you were 20 asked about the many patents and publications on 21 your CV earlier? 22 A. Yes. 23 Q. And do you recall that you agreed that 24 they were not relevant to the issues that you're 25 opining on in this case?</p>

<p style="text-align: right;">Page 170</p> <p>1 A. Yeah. So my understanding of that 2 question was that question was directing me do you 3 think your patents and publications are relevant to 4 the synthesis of nitrosamines, the detection of 5 nitrosamines, the synthesis of valsartan or 6 nitrosamines in valsartan. That's what I 7 understood those -- those questions to be about my 8 papers. And so I said no, they're not relevant. 9 But I think they are relevant in terms 10 of general organic chemistry and using DMF as a 11 solvent, for example, in chemistry. So they are 12 relevant in that respect. As an expert witness in 13 this particular case, my experience in publications 14 are very relevant. 15 Q. Doctor, do you recall that you testified 16 several times that you're not functioning as the 17 regulatory expert in this case; correct? 18 A. That's correct. 19 Q. Do you know if ZHP is presenting a 20 regulatory expert in connection with this 21 litigation? 22 A. Yes, Ali Afnan. 23 Q. Okay. And did you review his expert 24 report and deposition testimony? 25 A. Yes, I did.</p>	<p style="text-align: right;">Page 172</p> <p>1 introduce dimethylamine into the manufacturing 2 processes in which that DMF solvent was used? 3 A. No. When you read the term calculated as 4 dimethylamine content, as an analytical chemist you 5 know your total base content, total base content. 6 You're not thinking dimethylamine. And also those 7 numbers of those COAs were extremely low. Those 8 are the kind of numbers you look at and you say I 9 don't have to worry about this issue. These are 10 really low numbers. 11 MS. ROSE: All right. Thank you so much, 12 Doctor. That's all I have. 13 THE WITNESS: Thanks. 14 MR. SLATER: We're going to go off the 15 record. 16 MS. ROSE: Okay. 17 THE VIDEOGRAPHER: We're off the record 18 at 3:41 p.m. 19 (Break taken.) 20 THE VIDEOGRAPHER: We're back on the 21 record at 3:47 p.m. 22 E X A M I N A T I O N 23 BY MR. SLATER: 24 Q. I just have a few follow-up questions for 25 you.</p>
<p style="text-align: right;">Page 171</p> <p>1 Q. Okay. And did you rely on his opinions 2 with respect to regulatory issues? 3 A. With respect to regulatory issues, 4 absolutely, yes. 5 Q. Okay. Would you agree that you're an 6 expert in the field of organic chemistry? 7 A. Yes. 8 Q. And would you agree that you're an expert 9 in the field of process chemistry? 10 A. Yes. 11 MR. SLATER: Objection to both questions. 12 Leading. 13 BY MS. ROSE: 14 Q. Dr. Thompson, when you used DMF solvent 15 in chemical processes prior to the summer of 2018, 16 were you on notice that dimethylamine was present 17 in DMF? 18 A. No. 19 Q. Do you recall talking about the COAs that 20 were associated with the dimethylformamide solvent 21 that was used by ZHP? 22 A. Yes. 23 Q. Okay. Do you believe that those 24 certificates of analysis would have put ZHP on 25 notice that using dimethylformamide solvent would</p>	<p style="text-align: right;">Page 173</p> <p>1 A. Okay. 2 Q. You talked a little bit about what you 3 based your opinion on, and you said that one of the 4 things you're relying on is the two regulatory 5 bodies reviewed amendments. Those were amendments 6 to what? 7 A. Those -- those were amendments to the 8 original, I guess the -- so the -- the DMF they 9 changed from ten -- I'm doing my best to recall 10 this. They changed from ten to the triethylene 11 hydrochloride process. That was a DMF. And then 12 there were amendments to that DMF. I believe there 13 were four, maybe five amendments to that. Two of 14 those amendments were -- involved sodium nitrite 15 quenching. 16 Q. Did you read those amendments? 17 A. I read the -- I read the amendments that 18 Princeton had. And I'm not that savvy a regulatory 19 person to know if they -- the amendments that 20 Princeton, the drug product manufacturer had, would 21 be the same amendments that ZHP submitted to the 22 FDA. I don't think -- I don't know if they're the 23 same, but I read the ones that Princeton supplied, 24 the drug product manufacturer. 25 Q. You made clear you're not a regulatory</p>

<p style="text-align: right;">Page 174</p> <p>1 expert; right?</p> <p>2 A. Yes.</p> <p>3 Q. And you can't tell us right now, based on</p> <p>4 your own knowledge, what the FDA did with those</p> <p>5 amendments to evaluate them; right?</p> <p>6 A. I assume they read them.</p> <p>7 Q. You don't know who would have read them</p> <p>8 or what they would have done; right?</p> <p>9 A. I recall reading from various documents,</p> <p>10 like Afnan's, that they were read by chemists,</p> <p>11 organic chemists at those regulatory agencies were</p> <p>12 some of the people that read those.</p> <p>13 Q. You're not testifying that it's within</p> <p>14 your expertise to know what the FDA did when they</p> <p>15 reviewed those amendments; right?</p> <p>16 A. No. I'm assuming that the FDA read those</p> <p>17 with an eye towards safety. These --</p> <p>18 Q. I didn't mean to interrupt. Had you</p> <p>19 finished?</p> <p>20 A. Yeah. So I'm assuming the FDA read those</p> <p>21 documents with a particular concern about how that</p> <p>22 would affect the safety of the -- of the API.</p> <p>23 Q. You're joining that assumption, but you</p> <p>24 don't know that? That's not within your expertise;</p> <p>25 right?</p>	<p style="text-align: right;">Page 176</p> <p>1 A. That's correct.</p> <p>2 Q. You mentioned that you had reviewed</p> <p>3 Dr. Afnan's report; right?</p> <p>4 A. Yes.</p> <p>5 Q. I have your list -- your amended list of</p> <p>6 materials reviewed. I don't see any reference to</p> <p>7 his deposition. You did not see his deposition;</p> <p>8 correct?</p> <p>9 A. I can't -- I can't remember. I</p> <p>10 definitely read his report.</p> <p>11 Q. You told us before that everything was</p> <p>12 carefully written. I assume if you had read the</p> <p>13 deposition, it would be listed. And since it's</p> <p>14 not, that's not something you would have seen;</p> <p>15 correct?</p> <p>16 A. Yeah, that's correct.</p> <p>17 MS. ROSE: Object to form.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. You don't recall any specifics or</p> <p>20 anything you saw in a deposition of Afnan that's</p> <p>21 not listed, but there's nothing you independently</p> <p>22 recall about that; right?</p> <p>23 A. No, there's nothing I recall about it</p> <p>24 specific to him, no.</p> <p>25 Q. You testified you relied on Dr. Afnan's</p>
<p style="text-align: right;">Page 175</p> <p>1 A. That's correct.</p> <p>2 Q. You mentioned your CV, that there was</p> <p>3 something relevant within, I think, either the</p> <p>4 patents or publications you said with regard to</p> <p>5 general organic chemistry and the use of DMF. Are</p> <p>6 your specific -- any of these specific patents or</p> <p>7 publications specific to the use of DMF?</p> <p>8 A. No. Those -- they -- they would include</p> <p>9 syntheses that used DMF as a solvent, but they</p> <p>10 don't specifically zero in on studies of DMF</p> <p>11 itself. Just --</p> <p>12 Q. Does it talk about the use of the DMF as</p> <p>13 a solvent in any considerations of potential</p> <p>14 impurities and issues like that? Does that</p> <p>15 actually discuss that at issue which we have in</p> <p>16 this case?</p> <p>17 A. No, it just lists DMF as a solvent, not</p> <p>18 the -- there was no discussion in any of my work</p> <p>19 about the impurities of DMF.</p> <p>20 Q. And there's no discussion of</p> <p>21 dimethylamine as a potential impurity of DMF;</p> <p>22 right?</p> <p>23 A. That's right.</p> <p>24 Q. And there's no discussion of degradation</p> <p>25 of DMF to form dimethylamine; correct?</p>	<p style="text-align: right;">Page 177</p> <p>1 opinions on regulatory issues. In essence you</p> <p>2 would just be able to tell us, based on the reading</p> <p>3 the report, what his opinions were; correct?</p> <p>4 MS. ROSE: Object to form.</p> <p>5 THE WITNESS: Yeah. I mean, I viewed him</p> <p>6 as a gu -- a regulatory guru. I could see what he</p> <p>7 was saying. I could tell there was a lot of depth</p> <p>8 behind what he was saying. I relied on it as I</p> <p>9 would if I was talking to somebody at the FDA.</p> <p>10 Super qualified guy.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. What did you specifically rely on him</p> <p>13 for?</p> <p>14 A. So there was in -- in Ramin and Hecht's</p> <p>15 deposition testimony, there was numerous references</p> <p>16 to failure to do proper risk evaluation, GMP</p> <p>17 violations, you know, didn't -- didn't do this</p> <p>18 GM -- all this guidance, Q3, M7, Q9, Q10. There</p> <p>19 was a lot of references to regular -- FDA</p> <p>20 regulatory documents and how ZHP failed to follow</p> <p>21 any of it. And I thought Afnan systematically</p> <p>22 debunked every one of those assertions in their</p> <p>23 testimony.</p> <p>24 Q. Those are areas that you've already told</p> <p>25 us you're not an expert on and you're not going to</p>



<p style="text-align: right;">Page 178</p> <p>1 testify on; correct?</p> <p>2 A. That's right. But I relied on him, and</p> <p>3 he was debunking it, every one.</p> <p>4 Q. You mentioned that the certificates of</p> <p>5 analysis would not have placed ZHP on notice that</p> <p>6 the DMF would introduce dimethylamine. I wrote it</p> <p>7 down carefully. That's what you said. Do you</p> <p>8 recall that?</p> <p>9 A. Yes.</p> <p>10 Q. And you stand by what you told me when I</p> <p>11 questioned you that ZHP was certainly on notice of</p> <p>12 the potential that the DMF it was using could</p> <p>13 potentially introduce dimethylamine to the process?</p> <p>14 You still stand behind that testimony; correct?</p> <p>15 MS. ROSE: Object to the form.</p> <p>16 THE WITNESS: I think low-level people</p> <p>17 filing documents saw a line about alkalinity,</p> <p>18 calculated it as dimethylamine. But I don't think</p> <p>19 that ever put anybody on notice. Those words did</p> <p>20 not put anybody on notice that dimethylamine could</p> <p>21 be introduced to the process.</p> <p>22 And as I said before, the numbers</p> <p>23 were so low. They bought the best stuff, the</p> <p>24 highest quality. The numbers were so low,</p> <p>25 everybody would say this is not a problem. Let's</p>	<p style="text-align: right;">Page 180</p> <p>1 correct?</p> <p>2 MS. ROSE: Object to the form.</p> <p>3 THE WITNESS: Yeah, and I'm basing my</p> <p>4 opinion on the actual number. So the -- the half</p> <p>5 spec, this is the level it cannot exceed, which is</p> <p>6 a low number to begin with. The few COAs that I</p> <p>7 saw were way lower than that. So that's what I</p> <p>8 based my opinion that this is not a problem on.</p> <p>9 This would not alert them to a problem is the</p> <p>10 numbers I actually saw on the supplied material.</p> <p>11 That's what I --</p> <p>12 BY MR. SLATER:</p> <p>13 Q. In terms of what -- what that information</p> <p>14 should have triggered in terms of a risk</p> <p>15 assessment, you've already told us that's not your</p> <p>16 expertise. You're not opining on that; right?</p> <p>17 A. Yeah, formal risk assessment I'm</p> <p>18 not -- I'm not an expert on formal risk assessment.</p> <p>19 Q. And you didn't evaluate the risk</p> <p>20 assessment by ZHP? It's not something you talked</p> <p>21 about in your report; right?</p> <p>22 A. All I did was I read through the risk</p> <p>23 assessment that was in the deviation investigation</p> <p>24 report.</p> <p>25 Q. After the fact.</p>
<p style="text-align: right;">Page 179</p> <p>1 move on. So I --</p> <p>2 BY MR. SLATER:</p> <p>3 Q. I didn't --</p> <p>4 A. -- I don't agree that it would put them</p> <p>5 on notice. It would put them on relax.</p> <p>6 Q. You didn't do any review of any of ZHP's</p> <p>7 own internal testing of that DMF; correct?</p> <p>8 A. That's right, I did not.</p> <p>9 Q. You don't know what the actual numbers</p> <p>10 were in terms of how much dimethylamine might have</p> <p>11 actually been in that DMF because you haven't seen</p> <p>12 any documents of that testing; right?</p> <p>13 A. I haven't.</p> <p>14 MS. ROSE: Object to form.</p> <p>15 THE WITNESS: Yeah, I don't know what</p> <p>16 testing ZHP did. I know at J-STAR there would have</p> <p>17 been a lot of numbers on a COA, but we didn't do</p> <p>18 all -- we didn't repeat all those tests at J-STAR</p> <p>19 to prove our materials. We would only do a few.</p> <p>20 So I don't know what they did at ZHP.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. In terms of your opinions about the</p> <p>23 significance of the certificates of analysis,</p> <p>24 you're basing your opinions on what you did in your</p> <p>25 own work, in your own practice, at your own lab;</p>	<p style="text-align: right;">Page 181</p> <p>1 MS. ROSE: Object to the form.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. The deviation investigation report from</p> <p>4 after the fact.</p> <p>5 A. Yeah, after the fact. I read the</p> <p>6 deviation investigation after the fact. And the</p> <p>7 risk assessments all started with this is the</p> <p>8 problem and worked their way back. They</p> <p>9 never -- there was nothing in any risk assessments</p> <p>10 I saw that would allow you to forwardly identify an</p> <p>11 unknown.</p> <p>12 It was always this is the problem we</p> <p>13 have in our process. Where did this happen in</p> <p>14 our -- in our company. It was going backwards. So</p> <p>15 it reinforced my opinion that there was no risk</p> <p>16 assessment capable of letting them identify this</p> <p>17 problem.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. In terms of the standards that were</p> <p>20 applicable to ZHP in performing its risk assessment</p> <p>21 from the beginning of the development of the</p> <p>22 process, you already told me that's not something</p> <p>23 you opined on. It's not within your expertise;</p> <p>24 correct?</p> <p>25 A. Yes, that's true.</p>

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1 MR. SLATER: I don't have any other  
2 questions.

3 THE WITNESS: Great.

4 MS. ROSE: Okay. I don't have any  
5 questions either. Thank you very much, Doctor, for  
6 your time today.

7 THE WITNESS: Are you going for steak  
8 dinner, Adam? Where are you going?

9 THE VIDEOGRAPHER: One moment. The time  
10 is now 3:58 p.m. This concludes today's testimony  
11 from Dr. Andrew Thompson. We're now off the  
12 record.

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1 STATE OF WISCONSIN )  
2 ) ss.

3 COUNTY OF MILWAUKEE )

4 I, ANITA KORNBURGER, Registered  
5 Professional Reporter, do hereby certify that  
6 the preceding deposition was recorded by me and  
7 reduced to writing under my personal direction.

8 I further certify that said deposition was  
9 taken remotely, with all parties appearing by  
10 videoconference, on May 9, 2025, commencing at  
11 9:43 a.m. and concluding at 3:58 p.m.

12 I further certify that I am not a relative  
13 or employee or attorney or counsel of any of  
14 the parties, or a relative or employee of such  
15 attorney or counsel, or financially interested  
16 directly or indirectly in this action.

17 In witness whereof, I have hereunto set my  
18 hand and affixed my seal of office at  
19 Milwaukee, Wisconsin, this 13th day of May,  
20 2025.

21

22 

23 ANITA KORNBURGER, RPR

24

25 NJ CCR #30X100244300

My certification expires June 30, 2026.

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

## VERITEXT LEGAL SOLUTIONS

## COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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